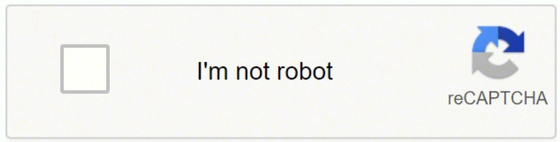

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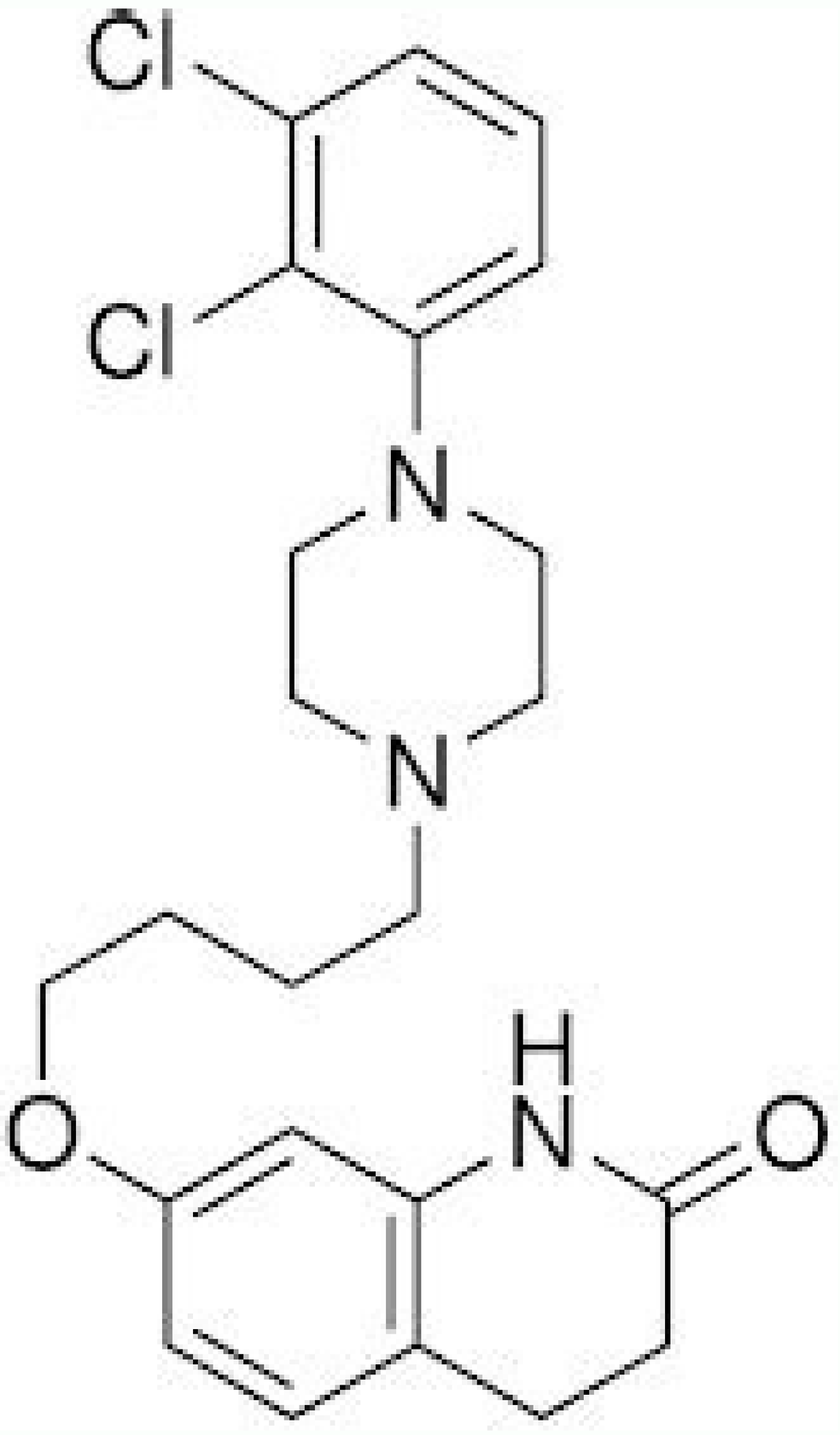
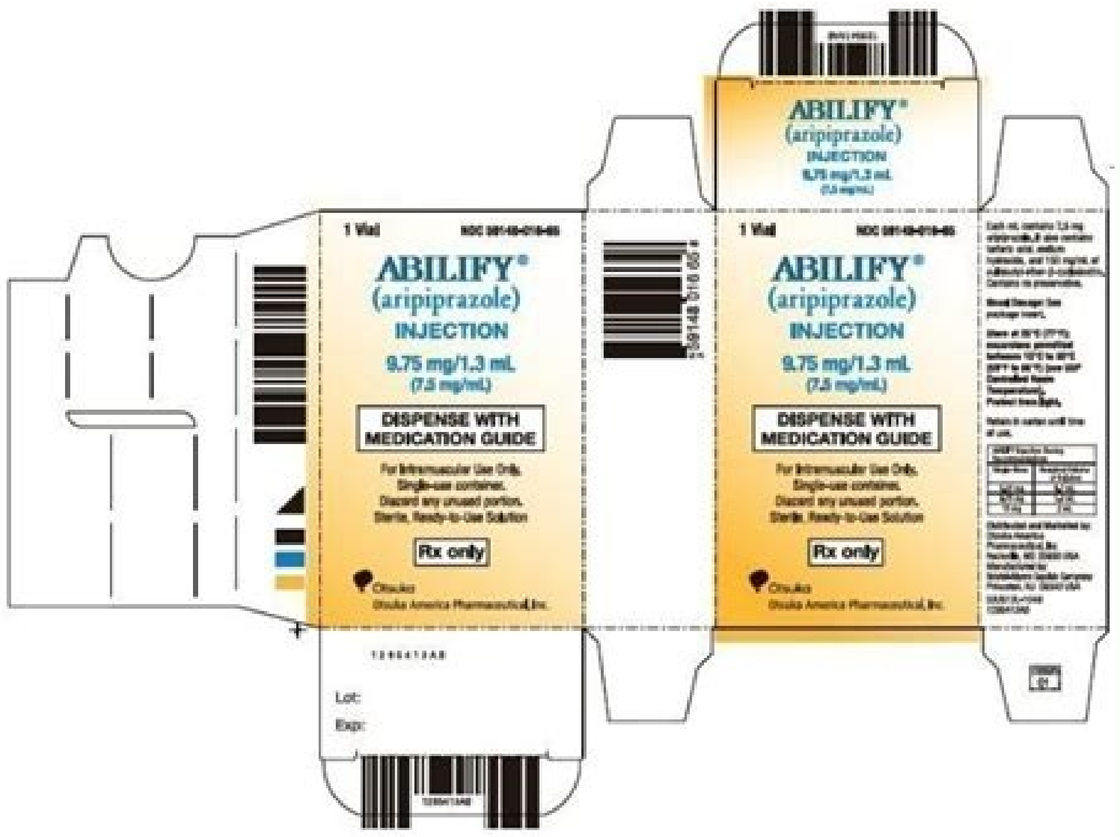
Abilify dosage forms available





Updated February 7, 2011 If you are a consumer or a patient, check out this version. APPENDIX OF REQUIRED INFORMATION These highlights do not include all the information you need to use ABILIFY safely and effectively. For ABILIFY, see the full information. ABILIFYÂ® (aripiprazole) TabletsABILIFY DISCMELTÂ® (aripiprazole) Oral Disintegrating TabletsABILIFYÂ® (aripiprazole) Oral SolutionABILIFYÂ® (aripiprazole) Injection for INTRAMUSCULAR U.S. Approved: 2002 Elderly Patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ABILIFY is not approved for the treatment of patients with dementia-related psychosis. (5.1) Children, adolescents and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders are at increased risk of suicidal thinking and behaviour. (5.2) Indications and use, Paediatric (6 to 17 years), Autistic Disorder-associated Irritability (1.4) 11/2009 Dosage and Administration, Paediatric (6-17 years), Autistic Disorder-associated Irritability (2.4) 11/2009 Warnings and Precautions, Leukopenia, Neutropenia and Agranuloc (5.7) 07/2009 ABILIFY is an atypical antipsychotic indicated as oral formulations for: Treatment of schizophrenia (1.1) Adults: Efficacy was established in four 4- to 6-week trials and one maintenance trial in patients with schizophrenia (14.1) Adole 13-17 Efficacy was established in a 6-week process in patients with schizophrenia (14.1) Acute treatment of male or mixed episodes associated with bipolar I disorder as monotherapy and as add-on to lithium or valproate (1.2) Adults: Efficacy was founded in four 3-week monotherapy trials and one 6-week additional trial in patients with male or mixed episodes (14.1) .2) Paediatric Patients (Age 10-17): Efficacy was established in a process of four weeks in patients with mixed or male episodes (14.2) (14.2) Treatment of Bipolar I Disorder (1.2) Adults: Efficacy has been established in a maintenance study (14.2) Conjunctive treatment of major depressive disorder (MDD) (1.3) Adults: Efficacy was established in two six-week studies in patients with MDD who had an inadequate response to antidepressant therapy during the current episode (14.3) Treatment of depressive disorder (14.3). irritability associated with autistic disorders (1.4) Paediatric patients (age 6-17 years): Efficacy efficacy was established in two eight-week studies in patients with autistic disorders (14.4) Â 194;Â Â Â as an injection for: Acute treatment of agitation associated with schizophrenia or bipolar I disorder (1.5) Adults: efficacy was established in three 24-hour trials in patients agitated with schizofren Manic/mixed episodes of bipolar disorder I (14.5) Initiative RecoeconsigliatedDoseMaximDose Schizophrenia ¢Â adults (2.1) 10-15 mg/day10-15 mg/day30/day Schizophrenia~ÔØ adolescents (2.1) 2/10/day30/day Bimaniaðˇ;;;;;;;; 14 844mg; adult monotherapy; 14 224th or as monotherapy, or with lithium, or with adolescents (2.1) valproate (2.2) 15 mg/day15 mg/day30 mg/day Bipolar mania ¢Â;Â paediatric patients: monotherapy or in addition to lithium or valproate (2.2) 2) 2 mg/day10/daymg 30/day As an add-on to antidepressants 2-5/day5/day mg/15 mg/day associated with autistic disorder _;128;Â paediatric patients (2.4) 2 mg/day5-10 mg/day15 mg/day15 mg/day15 mg/day Agitation associated with schizophrenia or bipolar mania Adults (2.5) 9.75 mg/1.3 mL1948;160;â3⁄4IM30 injected mg/Â Â Â Maximum daily doses 30 mg (2.5) tablets: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg (3) Oral tablets: 10 mg and 15 (3) Oral solution mg/mL (3) Injection: 9.75 mg/1 Adverse events (e.g. Transitional ischemic attack, including mortities) (5.1) Suicidality and antidepressants: increased risk of suicidality in children, adolescents and young adults with greater depressive disorder (5.2) Malignant neuroleptic syndrome: Manage with immediate intermediation and close Monitoring (5.3) Late Dyskinesia: stop if clinically appropriate (5.4) hyperglycemia and diabetes mellitus: monitor glucose regularly in patients with and at risk of diabetes (5.5) orthostatic hypotension: use with caution in patients with cardiovascular disease or cerebrovascular known (5.6) Leucopenia, neutropenia and agranulocytosis: were reported with antipsychotics, including Abilify. Patients with a history of a count of the clinically significant low white blood cells (WBC) or a leutropenia/neutropenia drug-induced should have their full blood number (CBC) monitored frequently during the first months of therapy and the suspension of the abilityfy should be considered to The first sign of a clinically significant decrease in the WBC in the absence of other causal factors (5.7) convulsions/vulsions the possibility of a suicide attempt is inherent in schizophrenia and bipolar disorder. High-risk patients supervised (5.11) have commonly observed adverse reactions (incidence â‰¥ 5% and at least twice as much as for placebo) were (6.2): adult patients with schizophrenia: Akathisia pediatric patients (from 13 to 17 years) with schizophrenia: Extrapyramid disorder, drowsiness and patients with Adult tremor (monotherapy) with bipolar mania: Akathisia, sedation, restlessness, tremors and extrapyramid disorders Adult PatientsAdditive with lithium or valproate) with bipolar disorder: Akathisia, insomnia and paediatric patients with extrapyramidal disorder (10 to ANNI) With bipolar mania: somnolence, extrapyramidal disorder, fatigue, nausea, akathisia, blurred vision, salivary hypersecretion, and vertigo adult patients with a major depressive disorder (additional treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue and blurred vision Paediatric patients (from six to 17 years) with autistic disorder: sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder and adult lethargy patients with agitation associated with schizophrenia or bipolar mania: nausea. To report suspected adverse reactions, contact Bristol-Myers Squib on 1-800-721-5072 or FDA at 1-800-FDA-1088 or www.fda. gov/medwatch Strong CYP3A4 (e. g. ketoconazole) or CYP2D6 (e. g. fluoxetine) Inhibitors will increase the stabilisation of drug concentrations; Reducing the abilify dose of one half if used concomitantly (2,6, 7.1), unless used as an additional treatment with antidepressants (2,6) inducers of CYP3A4 (e. g. carbamazepine) will decrease the stabilisation of drug concentrations; Double dose abilify when used concomitantly (2,6, 7.1) see 17 for patient advice Information and Drug Guide. Revised: 11/2009 Summary Box Warning (What is it?) Warnings: Increased mortality in elderly patients with elderly psychosis related to dementia and antidepressant drugs Elderly patients with psychosis related to dementia treated with antipsychotic drugs are at an increased risk of death drug users. Analysis of seventeen placebo-controlled trials (10-week fashion duration), largely in patients taking atypical antipsychotic drugs, revealed the risk of death in patients treated with 1,6 to 1,7-times the risk of death in patients treated with placebo. In the course of a typical process For ten weeks, the death rate in drug-treated patients was around 4,5%, compared to a rate of about 2,6% in the Placebo Group. Although the causes of death were varied, most of the dead cardiovascular (e.g. heart failure, sudden death) or infectious (e.g. pneumonia.) observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs can increase mortality. It is not clear until the results of an increase in mortality in observational studies can be attributed to the antipsychotic drug compared to certain characteristics of patients. abilify (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis [see warnings and precautions (5.1)]. in short-term studies on major depressive disorder (md) and other psychiatric disorders, antidepressants have increased the risk of suicidal thoughts and behaviors (suicides) in children, adolescents and young adults compared to placebo. anyone considering the use of abilify as an additional therapy or any other antidepressant in children, adolescents or young adults must balance such risk with clinical need. short-term studies showed no increase in the risk of suicide with antidepressants compared to placebo in adults over the age of 24; there has been a risk reduction with antidepressants compared to placebo in adults aged 65 or over. depression and some other psychiatric disorders are in turn associated with an increase in the risk of suicide. Patients of all age groups who start antidepressant therapy should be properly monitored and kept under close observation to detect clinical worsening, suicide or behavioral abnormalities. families and people who take care of them must be informed of the need for close observation and communication with the doctor prescribed. abilify is not approved for l'o in pediatric patients with depression [see warnings and preceptions (5.2)]] . 1 indications and1.1 abilify schizophrenia is indicated for the treatment of schizophrenia. The effectiveness of abilify was established in four clinical trials lasting 4-6 weeks in adults and in a 6-week study in adolescents (from 13 to 17 years.) The maintenance effectiveness wasin an adult study and can be extrapolated to adolescents [see CLINICAL studies (14.1)]. ABILIFY monotherapy is indicated for the acute and maintenance treatment of manic and mixed episodes associated with Bipolar I Disorder. Efficacy was established in four three-week monotherapy studies in adults and one four-week monotherapy study in paediatric patients (10 to 17 years of age). Maintenance efficacy has been demonstrated in a monotherapy study in adults and can be extrapolated to paediatric patients (10 to 17 years of age) [see CLINICAL STUDI (14.2)]. Adjunctive Therapy ABILIFY is indicated as add-on therapy to lithium or valproate for the acute treatment of episodes. Efficacy was established in an additional six-week study in adults and can be extrapolated to paediatric patients (10 to 17 years of age) [see CLINICAL STUDIES (14.2)]. 1.3 Adjunctive treatment of severe depressive disorder ABILIFY is indicated as add-on therapy to antidepressants for the treatment of major depressive disorders (MDD). Efficacy was established in two six-week studies in adults with MDD who had an inadequate response to antidepressant therapy during the current episode [see CLINICAL STUDI (14.3)]. 1.4 Irritation Associated with Autistic Disorder ABILIFY is indicated for the treatment of irritability associated with autistic disorders. Efficacy was established in two eight-week studies in paediatric patients (6 to 17 years of age) with irritability associated with autistic disorders (including symptoms of aggression towards others, intentional self-harm, temperamental fickle, and rapid mood changes) [see CLINICAL STUDIES (14. 1.5 Agitation Associated with Schizophrenia or Bipolar Mania ABILIFY Injection is indicated for the acute treatment of agitation associated with schizophrenia or bipolar disorder, or mixed. "Psychomotor agitation" is defined in DSM-IV as "excessive motor activity associated with a feeling of inner tension". interior." Agitation often manifests behaviours that interfere with their diagnosis and treatment (e.g., threatening behaviours, authentic or urgently distressing behaviours, or self-expecting behaviours), important clinicians for the use of intramuscular antipsychotic drugs to get immediate control of agitation. Efficacy was based on three short-term (24 hour) trials in adults (see clinical trials (14.5)). 1.6 Special considerations in the treatment of paediatric schizophrenia, bipolar I disorder and irritability associated with psychiatric disorders of autistic disorder in children and adolescents are often severe mental disorders with variable symptom profiles that are not always consistent with adult diagnostic criteria. It is recommended that psychotropic pharmacological therapy for paediatric patients be initiated only after a thorough diagnostic assessment and careful consideration of the risks associated with the treatment of the medicinal products. Drug treatment for pediatric patients with schizophrenia, bipolar I disorder and irritability associated with autistic disorder is indicated as part of a comprehensive treatment program that often includes psychological, educational and social interventions. 2 Dosage and Administration 2.1 Schizophrenia Adults Dose Selection: The recommended starting and target dose for Abilify is 10 mg/day or 15 mg/day administered on a once daily schedule without regard to meals. Abilify has been systematically evaluated and shown to be effective in a dose range of 10 mg/day to 30 mg/day when given as a tablet formulation; However, doses above 10 mg/day or 15 mg/day were not more effective than 10 mg/day or 15 mg/day. Dose increases should generally not be made before 2 weeks, the time required to reach steady state [see clinical trials (14.1)]. maintenance: maintaining effectiveness in schizophrenia has been demonstrated in a test involving patients with schizophrenia that had been symptomaticly stableantipsychotic medicines for periods of three months or more. These patients were discontinued with these medicines and randomised to ABILIFY 15 mg/di e or placebo, and relapses were observed [see CLINICAL STUDIES (14.1]. Patients should be reviewed periodically to determine the need to continue maintenance treatment. Adolescents Dose Selection: The recommended target dose of ABILIFY is 10 mg/die. Aripiprazole has been studied in adolescent patients aged between 13 and 17 years of schizophrenia at daily doses of 10 mg and 30 mg. The initial daily dose of tablet formulation in these patients was 2 mg, increased gradually to 5 mg after two days and up to the target dose of 10 mg after another two days. Subsequent dose increases should be made with increases of 5 mg. The 30 mg/die dose was not more effective than the 10 mg/die dose. ABILIFY can be administered independently of meals (see CLINICAL STUDIES (14.1). Maintenance treatment: The effectiveness of ABILIFY in the treatment of maintenance of schizophrenia in the adolescent population has not been evaluated. Although there is no evidence available to answer the question of how long the adolescent patient receiving ABILIFY should continue to receive the medicine, Maintenance efficacy may be extrapolated from adult data together with a comparison of the pharmacokinetic parameters of aripiprazole in adult and paediatric patients. Therefore, it is generally recommended that responsive patients continue beyond the acute response, but at the minimum dose necessary to maintain remission. Patients should be reviewed periodically to determine the need for maintenance treatment. No systematic data have been collected to specifically treat patients with schizophrenia who switch from other antipsychotics to ABILIFY or Concurrent administration with other antipsychotics. Although the immediate interruption of the previous antipsychotic treatment may be acceptable to some patients. patients.with schizophrenia, the more gradual interruption may be more appropriate for others. In all cases, the period of overlapping antipsychotic administration should be minimised. 2.2 Bipolar disorder I Adult dose selection: the starting and target dose recommended is 15 mg once a day as monotherapy or as additional therapy with lithium or valproate. ABILIFY can be given without regard to meals. The dose may be increased to 30/day depending on the clinical response. The safety of doses exceeding 30/day has not been evaluated in clinical studies [see CLINICAL STUDIES (14.2)]. Maintenance: Maintenance of efficacy in bipolar disorder I was demonstrated in a study with patients who had been symptomatically stable on ABILIFY Tablet (15 mg/day or 30 mg/day as monotherapy) for at least six consecutive weeks. These patients were discontinued by those medicines and randomized to ABILIFY at the same dose as they were stabilised, or on the placebo, and observed for relapse [see CLINICAL STUDIES (14.2)]. Patients should be reviewed periodically to determine the continued need for maintenance treatment. Paediatric patients Dose selection: The effectiveness of ABILIFY has been established in the treatment of paediatric patients from ten to 17 years of age with bipolar disorder I doses of 10 mg/day or 30/mg/day. The recommended dose of ABILIFY is 10 mg/day, monotherapy or additional therapy with lithium or valproate. The initial daily dose of tablet formulation in these patients was two mg/day, which was titrated to 5 mg/day after two days and to the target dose of 10 mg/day after two additional days. Subsequent dose increases should be given in five mg/days. ABILIFY can be given without regard to meals. [See CLINICAL STUDIES (14.2)] Maintenance treatment: the effectiveness of ABILIFY in the treatment of bipolar I in the paediatric population has not been evaluated. Although there is no evidence available to answer For how long the paediatric patient treated with ABILIFY should be maintained, the maintenance effectiveness can be extrapolated from adult data together with comparisons of the pharmacokinetic parameters of aripiprazole in adult and paediatric patients. Therefore, patients who respond may be considered for continued treatment beyond the acute response to the lowest dose needed to maintain remission. Patients should be reviewed periodically to determine the continued need for maintenance treatment. 2.3 Adjunctive treatment of severe depression disorder Adjunctive dose selection for adults: The recommended starting dose for ABILIFY as an additional treatment for patients already taking an antidepressant is from 2/day to 5 mg/day. The efficacy of ABILIFY as an additional therapy for major depressive disorder was established within a dose range of 2 mg/day to 15 mg/day. Dose adjustments up to five mg/day should be made gradually, at intervals not less than one week (see CLINICAL STUDIES (14.3)). Maintenance treatment: The efficacy of ABILIFY for the treatment of additional maintenance of major depressive disorders has not been evaluated. Although there is no evidence available to answer the question of how long the patient treated with ABILIFY should be maintained, patients should be periodically reassessed to determine the continued need for maintenance treatment. 2.4. Irritation Associated with autistic disorders Paediatric patients Dose selection: The efficacy of aripiprazole has been established in the treatment of paediatric patients 6-17 years of age with irritability associated with autistic disorders at doses of 5/day to 15 mg/day. The dosage of ABILIFY should be individualised according to tolerability and response. Dosage should be started at 2 mg/day. The dose should increased to 5 mg/day, with subsequent increases to 10 mg/day or 15 mg/day if necessary. Dose adjustments up to five mg/day should be made gradually, at intervals not less than one week (see CLINICAL STUDIES (14.4)). Maintenance Maintenance The effectiveness of ABILIFY for the maintenance of irritability associated with autistic disorder has not been assessed. 2.5 Agitation associated with schizophrenia or bipolar mania (in intramuscular injection) Adults A selection of the dose: the recommended dose for these patients is 9.75 mg. The effectiveness of injectable aripiprazole in the control of agitation in schizophrenia and bipolar mania was demonstrated in a dosage range from 5.25 mg to 15 mg. No additional benefit has been shown for 15 mg compared to 9,75 mg. A lower dose of 5.25 mg can be taken into account when clinical conditions justify it. If the agitation that justifies a second dose persists after the initial dose, cumulative doses can be given up to a total of 30 mg/day. However, the

effectiveness of repeated doses of aripiprazole by injection in agitated patients has not been systematically evaluated in controlled clinical studies. The safety of total daily doses greater than 30 mg or injections administered with a frequency greater than 2 hours has not been properly assessed in clinical studies [see CLINIC STUDIs (14.5)] . If an ongoing therapy is clinically indicated with aripiprazole, the oral aripiprazole in a range of 10 mg/die to 30 mg/die should be replaced as soon as possible [see DOSAGGIO AND SOMMINISTRATION (2.1 and 2.2)]. Administering ABILIFY Injection To administer ABILIFY Injection, aspire in the syringe the required volume of solution as shown in Table 1. Delete any portion not used. ABILIFY Injection is only for intramuscular use. Do not administer intravenous or subcutaneous. Inject slowly, deep into muscle mass. Before administration, parental medicines must be visually inspected to verify the absence of particles and color alterations, if the solution andExcuse me. 2.6 Dosage adjustments in adults are not usually indicated on the basis of age, gender, race, or renal or hepatic impairment (see SPECIFIC POPULATION USE (8.4-8.10)). Dose adjustment for patients taking aripiprazole concomitantly with strong CYP3A4 inhibitors: When co-administration of aripiprazole with strong CYP3A4 inhibitors such as ketoconazole or clarithromycin is indicated, the dose of aripiprazole should be reduced to half the usual dose. When the CYP3A4 inhibitor is withdrawn from the combination therapy, the dose of aripiprazole should be increased [see DRUG INTERACTIONS (7.1)]. Dose adjustment for patients taking aripiprazole concomitantly with potential CYP2D6 inhibitors: When co-administration of potential CYP2D6 inhibitors such as quinidine, fluoxetine or paroxetine with aripiprazole occurs, the dose of aripiprazole should be reduced to at least half of the dose. normal dose. When the CYP2D6 inhibitor is withdrawn from the combination therapy, the dose of aripiprazole should be increased [see DRUG INTERACTIONS (7.1)]. When adding ABILIFY to patients with severe depressive disorder, ABILIFY should be administered without dose adjustment as specified in DOSAGE AND SUBMITTION (2.3). Dose adjustment for patients taking potential CYP3A4 inducers: When a potential CYP3A4 inducer such as carbamazepine is added to aripiprazole therapy, the aripiprazole dose should be doubled. Further dose increases should be based on clinical assessment. When the CYP3A4 inducer is withdrawn from the combination therapy, the dose of aripiprazole should be reduced to 10 mg to 15 mg (see DRUG INTERACTITIONS (7.1)). 2.7 Dosage of oral solution The oral solution may be replaced with tablets on a mg-by-mg basis At dose level 25 mg. Patients receiving 30 mg tablets must receive 25 mg of the solution [see Pharmacology clinic (12.3)]. 2.8 Dosage of oral supplements tables The dosage dosage ABILIFY Orally Disintegration of tablets is the same as oral tablets [see DOSAGE AND ADMINISTRATION (2.1, 2.2, 2.3 and 2.4)]. 3.ADDITIONS FORMs AND STRENGHT ABILIFY Tablets are available as described in Table 2. ABILIFY DISCMELTIA ® (aripiprazole) Interchangeable tables are available as described in Table 3. ABILIFI194; 174; (aripiprazole) Oral solution (1 mg/mL) is a clear, colourless to pale yellow solution, supplied in baby-resistant bottles together with a calibrated oral dosing cup. ABILIFI194; 174; Injection for intramuscular use is a clear and colourless solution available as a ready-to-use solution, 9.75 mg/1.3 mL (7.5 mg/mL) in type 1 glass vials. 4 CONTRACTS A known hypersensitivity reaction to ABILIFY. Reactions ranged from itching/hives to anaphylaxis (see REAL REACTIONS (6.3)). 5.1.Use in elderly patients with dementia Increase in elderly patients with dementia-related psychosis treated with antipsychotic drugs is at greater risk of death. ABILIFY (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis (see BOXED WARNING). Cerebrovascular adverse events, including Stroke In placebo-controlled clinical studies (two flexible doses and a fixed dose study) of dementia-related psychosis, there has been an increase in the incidence of cerebrovascular adverse events (e. g. stroke, transient ischaemic attack), including fatalities. in patients treated with aripiprazole (mean age: 84 years; interval: 78-88 years). In the fixed dose study, there was a statistically significant dose response ratio for cerebrovascular adverse events in patients treated with aripiprazole. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis (see also BOXED WARNING). Safety experience in elderly patients with associated with Alzheimer's disease In three to ten weeks, placebo-controlled studies of aripiprazole aripiprazole Elderly patients with psychosis associated with Alzheimer's disease (n = 938; mean age: 82.4 years; range: 56-99 years), treatment emergent adverse events that were reported at Ã¥ 3% and Aripiprazole incidence at least twice for placebo were lethargy [placebo 2%, Aripiprazole 5%, somnolence (sedation) [Placebo 3%, Aripiprazole 8%], and incontinence (primarily urinary incontinence) [placebo 1%, Aripiprazole 5%], Excessive salivation [placebo 0%, Aripiprazole 4%] and vertigo [placebo 1%, Aripiprazole 4%]. The safety and efficacy of habilify in the treatment of patients with dementia-associated psychosis have not been established. If the prescriber elects to treat such patients with habilify, vigilance should be exercised, particularly for the emergence of swallowing difficulties or excessive sleepiness, which could predispose to accidental injury or aspiration [see also boxed warning]. 5.2 Clinical worsening of depression and suicidal patients with major depressive disorder (MDD), both adult and paediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour (suicide) or unusual changes in behaviour, whether they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and some other psychiatric disorders, and these oneself are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may play a role in causing worsening depression and the emergence of suicidal behavior in some patients during the early stages of treatment. Pooled analyses of short-term placebo-controlled antidepressant drugs (SSRIs and others) have shown that these drugs increase the risk of suicidal thinking and behaviour in children, adolescents and young adults (age 18-24) with MDD and other psychiatric disorders. Short term did not show an increased risk of suicide with antidepressants compared to placebo in adults over 24 years of age; there was a reduction with antidepressants compared to placebo in adults over 65 years of age. Pooled analyses of placebo-controlled trials in children and adolescents with MDD, Obsessive Compulsive Disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with psychiatric disorders or MDD included a total of 295 short-term trials (mean duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in the risk of suicide between drugs, but a trend toward an increase in younger patients for almost all drugs studied. There were differences in the absolute risk of suicide across the different indications, with the highest incidence in MDD. The differences in risk (drug vs. placebo), however, were relatively stable within age and across indications. These risk differences (drug-placebo differences in the number of suicides per 1000 treated patients) are provided in Table 4. No suicides occurred in any of the pediatric processes. There have been suicides in adult trials, but the number was not enough to reach any conclusion about the drug effect on suicide. It is not known whether the suicide risk extends to long-term use, i.e. beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression. All patients treated with antidepressants for any indication should be monitored closely and monitored for clinical worsening, suicide and unusual changes in the especially during the first months of a course of pharmacological therapy, or sometimes dose changes, or increases or decreases. The Symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsiveness, akathisia (psychomotor agitation), hypomania and mania have been reported in adult and paediatric patients treated with antidepressants for MDD and other indications, both psychiatric and non-psychiatric. Although no causal link has been established between the onset of these symptoms and the worsening of depression and/or the onset of suicidal impulses, it is feared that these symptoms may be precursors to the onset of suicides. Consideration should be given to changing the treatment regimen, including the possibility of discontinuing treatment, in patients whose depression is persistently worse, or who are experiencing emerging suicides or symptoms that could be precursors to worsening depression or suicide, especially if these symptoms are severe, sudden onset, or were not part of the patient's symptoms. Families and operators of patients treated with antidepressants for severe depressive disorder or other indications, both psychiatric and non-psychiatric, should be advised of the need to monitor patients for the occurrence of agitation, irritability, or unusual changes in behaviour and other symptoms described above, in addition to suicides, and report these symptoms immediately to healthcare providers. This monitoring should include daily observation by families and health professionals. The requirements for ABILIFY should be written for the minimum amount of tablets compatible with good patient management in order to reduce the risk of overdose. Bipolar disorder screening patients: a severe depressive episode may be the initial presentation of bipolar disorder. It is generally considered (although not established in controlled studies) that the treatment of this episode with alone can increase the precipitation probability of a mixed / manic episode in patient patients risk of bipolar disorder. It is not known whether one of the symptoms described above represents such a conversion. However, patients with depressive symptoms should be adequately monitored before starting treatment with an antidepressant to determine whether they are at risk of bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder and depression. It should be noted that ABILIFY is not approved for the treatment of depression in the paediatric population. 5.3 Malignant Neuroleptic Syndrome (NMS) A potentially fatal set of symptoms sometimes called Malignant Neuroleptic Syndrome (NMS) may occur with the administration of antipsychotic medicines, including aripiprazole. Rare cases of NMS have occurred during treatment with aripiprazole in the world clinical database. The clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure. The diagnostic evaluation of patients with this syndrome is complicated. When a diagnosis is made, it is important to exclude cases where the clinical presentation includes both serious medical diseases (e.g. pneumonia, systemic infections) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in differential diagnosis include central anticholinergic toxicity, thermal stroke, drug fever and primary central nervous system disease. The management of NMS should include: 1) the immediate discontinuation of antipsychotics and other non-essential concomitant therapy medicinal products; 2) intensive symptomatic treatment and medical monitoring; and 3) all serious concomitant medical problems for which specific treatments are available. There is no one agreement on specific pharmacological treatment regimens for uncomplicated NMS. If a patient requires antipsychotic treatment after recovery from NMS, the potential reintroduction of pharmacological therapy should be carefully considered. The patient should be closely monitored as NMS recurrence has been reported. 5.4 Late dyskinesia A syndrome of potentially irreversible, involuntary, discinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be higher among the elderly, especially older women, it is impossible to rely on prevalence estimates to predict, at the beginning of antipsychotic treatment, which patients could develop the syndrome. It is not known whether antipsychotic drugs differ in their potential to cause late dyskinesia. The risk of developing late dyskinesia and the likelihood of irreversible dyskinesia is considered to increase as the duration of treatment increases and the total cumulative dose of antipsychotic drugs administered to the patient increases. However, the syndrome may develop, although much less commonly, after relatively short periods of treatment at low doses. There is no known treatment for established cases of late dyskinesia, even if the syndrome may give way, partially or completely, if the antipsychotic treatment is withdrawn. The antipsychotic treatment itself, however, can suppress (or partially suppress) the signs and symptoms of the syndrome and, therefore, can mask the underlying process. The effect of symptomatic suppression on the long term of the syndrome is not known. In view of these considerations, ABILIFY should be prescribed in such a way as to minimise the occurrence of late onset dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients suffering from a chronic illness (1) that is known respond to antipsychotic drugs and (2) for which alternative treatment is possible, equally effective, effective, potentially less harmful treatments are not available or appropriate. In patients in need of chronic treatment, the shortest dose and duration of treatment leading to a satisfactory clinical response should be sought. The need to continue treatment should be reviewed periodically. If signs and symptoms of late dyskinesia appear in a patient with ABILIFY, discontinuation of therapy should be considered. However, some patients may require treatment with ABILIFY despite the presence of the syndrome. 5.5 Hyperglycaemia and Diabetes Mellitus Hyperglycaemia, in some extreme cases associated with ketoacidosis or coma or hypermolar death, has been reported in patients treated with atypical antipsychotics. Few cases of hyperglycaemia have been reported in patients treated with ABILIFY (see ADVERSE REACTIONS (6.2, 6.3)). Although fewer patients have been treated with ABILIFY, it is not known whether this more limited experience is the only reason for the lack of such relationships. The assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increase in the underlying risk of diabetes mellitus in patients with schizophrenia and the increase in the incidence of diabetes mellitus in the general population. Given this confusion, the relationship between atypical antipsychotic use and hyperglycaemic related adverse events is not fully understood. However, epidemiological studies not including ABILIFY suggest an increased risk of hyperglycaemic-related adverse events in patients treated with atypical antipsychotics included in these studies. Poiche. © ABILIFY was not marketed at the time of these studies, it is not known whether ABILIFY is associated with this increased risk. No precise risk estimates are available for hyperglycaemic-related adverse events in patients treated with atypical antipsychotics. Patients with diabetes mellitus confirmed that: started with atypical antipsychotics should be monitored regularly for worsening glucose control. Patients with risk factors for diabetes mellitus (e. g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose tests at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycaemia, including polydipsia, polyuria, polyphagia and weakness. Patients who develop symptoms of hyperglycaemia during treatment with atypical antipsychotics should undergo fasting blood glucose tests. In some cases, hyperglycaemia resolved when the atypical antipsychotic was discontinued; However, some patients have requested continued anti-diabetic treatment despite discontinuation of the suspected drug. 5.6 Orthostatic hypotension Aripiprazole may cause orthostatic hypotension, possibly because of its receptor antagonism is 177; 1-adrenergic. The incidence of associated short-term orthostatic hypotension episodes, controlled placebo studies in adult patients on oral ABILIFY (n=2467) included (aripiprazole incidence, placebo incidence) orthostatic hypotension (1%, 0.3%), postural dizziness (0.5%, 0.3%), and syncope (0.5%, 0.4%); Paediatric patients 6-17 years of age (n=611) on ABILIFY oral included orthostatic hypotension (0.5%, 0%), postural dizziness (0.3%, 0%), and syncope (0.2%, 0%); Injection (n=501) included orthostatic hypotension (0.6%, 0%), postural dizziness (0.2%, 0.5%), and syncope (0.4%, 0%). The incidence of a significant orthostatic change in blood pressure (defined as a decrease in systemic blood pressure Hg accompanied by an increase in heart rate 25 when comparing supine values) aripiprazol was not significantly different from placebo (activation of aripiprazole, placebo incidence): in oral adult aripiprazole-treated patients (4%, 2%), in oral pediatricsThe patients of age between 6 and 17 years (0.2%, 0.1%), or in aripiprazole patients treated injection (3%, 2%). Aripiprazole must be used with caution in patients with cardiovascular disease note (history of myocardial infarction or ischemic heart disease, cardiac failure or conduction abnormalities), cerebrovascular disease or conditions that would have prepared patients to hypotension (dehydration, hypovolemia and treatment with antihypertensive drugs). If the parenteral benzodiazepine therapy is considered necessary in addition to the aripiprazole injection treatment, patients must be monitored for excessive sedation and for orthostatic hypotension [see pharmacological interactions (7.3)]. 5.7 Leucopenia, Neutropenia and Agranulocytosis class effect: in clinical trial and / or postmarketing experience, Leucopenia / Neutropenia events have been reported temporally related to antipsychotic agents, including Abilify. Agraranulocytosis has also been reported. Possible risk factors for leukopenia / neutropenia include the number of pre-existing low white blood blood cells (WBC) and the history of drug-induced neutropenia. Patients with a history of a clinically significant low WBC or drug-induced neutropenia should have their complete blood count (CBC) frequently monitored during the first months of therapy and the suspension of disability should be considered at the first sign of A clinically significant WBC decline in the absence of other causal factors. Patients with clinically significant neutropenia must be carefully monitored for fever or other symptoms or signs of infection and promptly treated if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count

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