

APPROVED PATIENT INFORMATION LEAFLET**Dr. Reddy's Laboratories (Pty) Ltd.
XOPHANU ODT (orodispersible tablets)****SCHEDULING STATUS:****S5****XOPHANU ODT 10 mg, orodispersible tablets****XOPHANU ODT 15 mg, orodispersible tablets****Aripiprazole****Contains sugar: lactose monohydrate****Contains sweetener: aspartame****XOPHANU ODT 10 mg:**

Each orodispersible tablet contains 1,00 mg Aspartame (E 951) and 95,05 mg lactose (as monohydrate).

XOPHANU ODT 15 mg:

Each orodispersible tablet contains 1,50 mg Aspartame (E 951) and 142,58 mg lactose (as monohydrate).

Read all of this leaflet carefully before you start taking XOPHANU ODT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- XOPHANU ODT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What XOPHANU ODT is and what it is used for

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2. What you need to know before you take XOPHANU ODT
3. How to take XOPHANU ODT
4. Possible side effects
5. How to store XOPHANU ODT
6. Contents of the pack and other information

1. What XOPHANU ODT is and what it is used for

Schizophrenia:

XOPHANU ODT is indicated for the treatment of schizophrenia and for the maintenance of clinical improvement in adults.

XOPHANU ODT is one of a group of medicines called antipsychotics. It is used to treat adults suffering from a disease characterized by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

Bipolar Mania:

XOPHANU ODT is indicated for the treatment of acute manic episodes associated with Bipolar I Disorder and for prevention of recurrence of new manic episodes in patients who experienced predominantly manic episodes and who responded to XOPHANU ODT treatment.

XOPHANU ODT is used to treat adults who suffer from a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability.

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2. What you need to know before you take XOPHANU ODT**Do not take XOPHANU ODT**

- if you are allergic (hypersensitive) to aripiprazole or any of the other ingredients of XOPHANU ODT (listed in Section 6).
- if you are younger than 18 years of age.

Warnings and precautions**Special care should be taken with XOPHANU ODT:**

- Suicidal thoughts and behaviours have been reported during aripiprazole treatment. Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself.

Before you start taking XOPHANU ODT, tell your doctor if you suffer from any of the following:

- cardiovascular diseases (diseases of the heart and circulation), family history of cardiovascular disease, stroke or "mini stroke", abnormal blood pressure
- blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots.
- restlessness, tremors, uncontrolled muscle contraction and bodily movements, no facial expression, fast and irregular breathing and drooling.
- involuntary, irregular muscle movements, especially in the face.
- fits (seizures/ epilepsy).
- if you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.
- high blood sugar (characterised by symptoms such as excessive thirst, passing of large

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amounts of urine, increase in appetite and feeling weak), or a family history of diabetes.

Tell your doctor, pharmacist, nurse or other health care provider:

- if you develop difficulty breathing or other allergic reactions such as rash or swelling.
- if you notice that your weight increases.
- if you suffer from pain when swallowing.
- if you have a past experience with excessive gambling or compulsive shopping or if you or your family/caregiver notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.
- if you are taking medicines for attention deficit hyperactivity disorder (ADHD).
- if you develop muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heartbeat while taking XOPHANU ODT.
- if you start feeling sleepy, or dizzy. XOPHANU ODT may cause sleepiness, fall in blood pressure when standing up, dizziness and changes in your ability to move and balance, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have some debility.
- XOPHANU ODT may cause difficulty controlling core body temperature or overheating, take appropriate care when taking XOPHANU ODT if you will be experiencing conditions which may contribute to an elevation in core body temperature, e.g. exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

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Children and adolescents

XOPHANU ODT is not for use in children and adolescents.

Other medicines and XOPHANU ODT

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Taking XOPHANU ODT with some medicines may mean the doctor will need to change your dose of XOPHANU ODT or the other medicines.

Tell your doctor if you are taking the following:

- medicines to treat high blood pressure. XOPHANU ODT may increase the effect of medicines used to lower blood pressure.
- diltiazem (a medicine used to treat high blood pressure and to control angina (severe chest pain))
- medicines to correct heart rhythm e.g., quinidine
- medicines for depression e.g., paroxetine, fluoxetine, escitalopram, St. John's Wort
- antifungal medicines e.g., ketoconazole, itraconazole
- medicines used to treat epilepsy (fits) e.g., phenobarbital and phenytoin, primidone and carbamazepine
- medicines to treat HIV infections e.g., efavirenz, nevirapine, and protease inhibitors e.g., indinavir, ritonavir
- certain antibiotics to treat tuberculosis e.g., rifabutin, rifampicin.

These medicines may increase the risk of side effects or reduce the effect of XOPHANU ODT; if you get any unusual symptom taking any of these medicines together with XOPHANU ODT you should see your doctor or healthcare provider.

Medicines that increase the level of serotonin are typically used in conditions including

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depression, generalised anxiety disorder, obsessive-compulsive disorder (OCD) and social phobia as well as migraine and pain:

- triptans, tramadol and tryptophan used for conditions including depression, generalised anxiety disorder, obsessive compulsive disorder (OCD) and social phobia as well as migraine and pain
- selective-serotonin-reuptake-inhibitors (SSRIs) (such as paroxetine and fluoxetine) used for depression, OCD, panic and anxiety
- other anti-depressants (such as venlafaxine and tryptophan) used in major depression
- tricyclic's (such as clomipramine and amitriptyline) used for depressive illness
- St John's Wort (*Hypericum perforatum*) used as a herbal remedy for mild depression
- pain killers (such as tramadol and pethidine) used for pain relief
- triptans (such as sumatriptan and zolmitriptan) used for treating migraine.

These medicines may increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with XOPHANU ODT, you should see your doctor.

XOPHANU ODT with alcohol

- Alcohol should be avoided when taking XOPHANU ODT.

Pregnancy and Breastfeeding

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If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking XOPHANU ODT.

- XOPHANU ODT may cause harm to your unborn child if you are taking it while being pregnant. You should not use XOPHANU ODT if you are pregnant.
- The following symptoms may occur in newborn babies, of mothers that have used XOPHANU ODT in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Be sure to tell your doctor immediately if you are breastfeeding.

You should not take XOPHANU ODT if you are breastfeeding.

Driving and using machines

Drowsiness, dizziness or vision problems may occur after taking XOPHANU ODT. If this happens, do not drive or use any tool or machines. Ask your doctor if you are not sure. It is not always possible to predict to what extent XOPHANU ODT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which XOPHANU ODT affects them.

XOPHANU ODT contains lactose, aspartame and sodium

XOPHANU ODT contains lactose (which is a type of sugar).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking XOPHANU ODT.

XOPHANU ODT contains aspartame.

XOPHANU ODT 10 mg contains 1,00 mg aspartame in each orodispersible tablet.

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XOPHANU ODT 15 mg contains 1,50 mg aspartame in each orodispersible tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

XOPHANU ODT orodispersible tablets contain sodium. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE XOPHANU ODT

Do not share medicines prescribed for you with any other person.

Always take XOPHANU ODT exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

For Schizophrenia:

XOPHANU ODT can be started at a dose of 10 or 15 mg/day and thereafter the usual dose is 15 mg once a day. However, your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

For Bipolar Mania:

XOPHANU ODT is started at a dose of 15 mg/day, once a day.

Your doctor will prescribe the dose recommended for you up to a maximum of 30 mg once per day.

Try to take the XOPHANU ODT tablet at the same time each day. It does not matter whether you take it with or without food.

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Do not open the blister until ready to administer. For single tablet removal, open the package and peel back the foil on the blister to expose the tablet. Do not push the tablet through the foil because this could damage the tablet. Immediately upon opening the blister, using dry hands, remove the tablet and place the entire orodispersible tablet on the tongue. Tablet disintegration occurs rapidly in saliva. The orodispersible tablet can be taken with or without water.

Alternatively, disperse the tablet in water and drink the resulting suspension.

Even if you feel better, do not alter or discontinue the daily dose of XOPHANU ODT without first consulting your doctor.

If you have the impression that the effect of XOPHANU ODT is too strong or too weak, talk to your doctor or pharmacist.

If you take more XOPHANU ODT than you should

If you realise that you have taken more XOPHANU ODT than you should (or if someone else has taken your XOPHANU ODT), contact your doctor, pharmacist or other health care provider immediately. If neither is available, contact the nearest hospital or poison control centre and take the pack of XOPHANU ODT with you.

Patients who have taken too much XOPHANU ODT have experienced the following symptoms:

- Increased blood pressure, drowsiness or sleepiness, rapid heartbeat, vomiting, loss of consciousness, abnormal rhythms of the heart.

Other symptoms may include:

- acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing,

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sweating.

- muscle stiffness, and drowsiness or sleepiness, slower breathing, choking, high or low blood pressure, abnormal rhythms of the heart.

If you forget to take XOPHANU ODT

- If you miss a dose of XOPHANU ODT, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only a single dose at the usual time.
- Do not take two doses at the same time to make up for the missed dose. Do not take more than the daily amount of XOPHANU ODT that has been prescribed for you in one day.

If you stop taking XOPHANU ODT

- Unless your doctor instructs you to stop treatment, it is important to continue taking XOPHANU ODT.
- Do not stop taking your tablets without the advice of your doctor, even if you feel better.
- If you have any further questions on the use of this product, ask your doctor, pharmacist or other healthcare provider.

4. Possible side effects

XOPHANU ODT can have side effects.

Not all side effects reported for XOPHANU ODT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XOPHANU ODT, please consult your health care provider for advice.

If any of the following happens, stop taking XOPHANU ODT and tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at

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your nearest hospital:

- swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing
- throat tightness, shortness of breath and wheezing.

Allergic reactions, including death, can happen in patients taking XOPHANU ODT even after only one dose.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to XOPHANU ODT. You may need urgent medical attention or hospitalisation.

Tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- thoughts of suicide, suicide attempt and suicide
- combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic malignant syndrome), aggressive agitation
- seizure
- life-threatening irregular heartbeat, (including so called QT prolongation seen with ECG monitoring)
- stopping of the heart
- blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to XOPHANU ODT. You may need urgent medical attention or hospitalisation.

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Tell your doctor, pharmacist or healthcare provider if you notice any of the following:**Frequent side effects:**

- trouble sleeping, restlessness, feeling anxious
- akathisia (an uncomfortable feeling of inner restlessness and a compelling need to move constantly i.e. unable to keep still, difficulty sitting still)
- movement disorder
- uncontrollable twitching, jerking or writhing movements
- headache, feeling dizzy, trembling or shaking, drowsiness
- blurred vision
- light-headedness, feeling like fainting or fainting when sitting up or getting up (orthostatic hypotension) – Schizophrenia condition
- nausea, vomiting, more in saliva than usual in the mouth, constipation, heartburn/indigestion, abdominal discomfort
- fast heart rate – Schizophrenia condition
- sleepiness
- muscle stiffness – Mania condition
- lack of energy and strength
- feeling tired.

Less frequent side effects:

- increased or decreased blood levels of the hormone prolactin
- feeling sad (depression)
- muscle disorder causing twisting movements (dystonia)
- eye sensitivity to light
- fast heart rate – Mania condition

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- light-headedness, feeling like fainting or fainting when sitting up or getting up (orthostatic hypotension) – Mania condition
- swelling of hands, ankles or feet (peripheral oedema)

Side effects with unknown frequencies:

- low levels of white blood cells
- low levels of blood platelets
- allergic reaction (e.g., swelling in the mouth, tongue, face and throat, itching, hives)
- onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma
- low sodium level in the blood
- loss of appetite (anorexia)
- high levels of sugar in the blood (hyperglycaemia)
- a disease in which your body is unable to produce or respond to the hormone insulin resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood and urine (diabetes)
- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
 - strong impulse to gamble excessively despite serious personal or family consequences
 - altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive
 - uncontrollable excessive shopping
 - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)
 - a tendency to wander away.

Tell your doctor if you experience any of these behaviours; he/she will discuss ways of

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managing or reducing the symptoms.

- feeling aggressive
- agitation
- nervousness
- serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles)
- speech disorder
- uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia)
- restless legs
- double vision (diplopia)
- fixation of the eyeballs in one position
- sudden unexplained death
- slower heartbeat
- high blood pressure
- fainting
- accidental inhalation of food with risk of pneumonia (lung infection)
- spasm of the muscles around the voice box
- hiccups
- inflammation of the pancreas
- difficulty swallowing
- diarrhoea
- stomach discomfort
- liver failure

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- inflammation of the liver
- yellowing of the skin and white part of eyes
- reports of abnormal liver tests values
- skin rash
- skin sensitivity to light
- hair loss (alopecia)
- excessive sweating
- serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia)
- abnormal muscle breakdown which can lead to kidney problems
- muscle pain
- stiffness
- prolonged abnormal muscle contractions
- involuntary loss of urine (incontinence)
- difficulty in passing urine
- withdrawal symptoms in newborn babies in case of exposure during pregnancy
- prolonged and/or painful erection
- difficulty controlling core body temperature or overheating
- chest pain
- weight loss
- weight gain

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- in blood tests: increased or fluctuating blood sugar, increased glycosylated haemoglobin, increased creatine phosphokinase
- prolonged painful erections (priapism)
- overheating (fever) and difficulty to control body temperature, chest pain, swelling of hands and feet
- changes in blood tests.

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of XOPHANU ODT.

5. How to store XOPHANU ODT

Store at or below 25 °C.

Keep the original package in order to protect from moisture.

This medicine does not require any special storage conditions.

Do not store in a bathroom.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Do not use after the expiry date stated on the carton.

Store all medicines out of reach of children.

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6. Contents of the pack and other information**What XOPHANU ODT contains**

The active substance is aripiprazole.

XOPHANU ODT 10 mg:

Each orodispersible tablet contains aripiprazole 10 mg.

XOPHANU ODT 15 mg:

Each orodispersible tablet contains aripiprazole 15 mg.

The other ingredients are Aspartame (E951), Croscarmellose sodium, Lactose monohydrate, Magnesium stearate, Microcrystalline cellulose (E460), Silica Colloidal Anhydrous, Iron oxide red (E172) – only for 10 mg, Iron oxide yellow (E172) – only for 15 mg

Vanilla flavour (containing maltodextrin, acacia gum, propylene glycol, benzyl alcohol and vanilla flavouring).

What XOPHANU ODT looks like and contents of the pack**XOPHANU ODT 10 mg:**

Round, flat, pink tablets, engraved with '10' on one side and plain on the other side.

XOPHANU ODT 15 mg:

Round, flat, yellow tablets, engraved with '15' on one side and plain on the other side.

XOPHANU ODT 10, 15 mg:

Aluminium-Aluminium paper peel-off blisters, each blister contains 10 tablets, 3 X10's pack.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd

Block B, 204 Rivonia Road

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**Dr. Reddy's Laboratories (Pty) Ltd.
XOPHANU ODT (orodispersible tablets)**

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South Africa

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XOPHANU ODT 15 mg: 57/1.2/0644