

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PINOMAZ 100 mg CR controlled release film coated tablets

PINOMAZ 200 mg CR controlled release film coated tablets

PINOMAZ 400 mg CR controlled release film coated tablets

Carbamazepine

PINOMAZ CR is sugar and sodium free.

Read all of this leaflet carefully before you start taking PINOMAZ CR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PINOMAZ CR 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 PINOMAZ CR is and what it is used for
2. What you need to know before you take PINOMAZ CR
3. How to take/use PINOMAZ CR
4. Possible side effects
5. How to store PINOMAZ CR
6. Contents of the pack and other information

1. What PINOMAZ CR is and what it is used for

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PINOMAZ CR belongs to a group of medicines called antiepileptics (medicine for seizures), it can also modify some types of pain and can control mood disorders.

PINOMAZ CR is used to:

- treat some forms of epilepsy
- help control serious mood disorders, certain psychiatric conditions (mania episodes of bipolar mood disorders and a certain type of depression).
- treat a painful condition of the face called trigeminal neuralgia
- treat a painful condition of the back of the tongue, back of the throat, or the area near the tonsils, sometimes spreading to the ear or the area at the back of the jaw called glossopharyngeal neuralgia.

2. What you need to know before you take PINOMAZ CR

Do not take PINOMAZ CR:

- if you are hypersensitive (allergic) to carbamazepine or to any of a related group of medicines known as tricyclic antidepressants (such as amitriptyline or imipramine) or to any of the ingredients of PINOMAZ CR (see section 6)
- if you have severe heart problems
- if you have ever had problems with your bone marrow
- if you have a blood disorder called porphyria
- if you have taken medicines called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days
- if you are breastfeeding
- if you have a history of serious skin rashes (Stevens- Johnson syndrome, toxic epidermal necrolysis) when taking medicine. The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often

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preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms), and the rash may progress to widespread blistering and peeling of the skin.

Warnings and precautions

Take special care with PINOMAZ CR:

- if you have blood illnesses (including those caused by other medicines) e.g., low platelet or white blood cell counts. If any of the following occurs, please consult your doctor immediately: fever, sore throat, rash, ulcers in the mouth, easy bruising, tiny round, brown-purple spots due to bleeding under the skin or a rash of purple spots due to small blood vessels leaking blood into the skin appear
- serious skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of PINOMAZ CR (see section 2). These serious skin reactions can be more common in people from some Asian countries. The risk of these reactions in patients of Han Chinese or Thai origin may be predicted by testing a blood sample of these patients. Your doctor should be able to advise if a blood test is necessary before taking this medicine. If you develop a rash or these skin symptoms, stop taking PINOMAZ CR and contact your doctor immediately. Other skin reactions may also occur e.g., a flat or raised red bump on the skin or a widely spread-out rash.
- if you have ever shown unusual sensitivity (rash or any other signs of allergy) to carbamazepine, oxcarbazepine or to any other medicines. It is important to note that if you are allergic to carbamazepine, the chances are that you could also have an allergic reaction to oxcarbazepine.
- if you suffer from the sort of epilepsy where you get mixed seizures (fits) which include absences (typical or atypical). PINOMAZ CR may increase your seizures. If you experience an increase in seizures, immediately stop taking this medicine and inform your doctor.
- if you have or have a history of liver disease or if you are elderly.

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- if you have kidney disease – your doctor will want to perform kidney function tests before and during treatment to monitor your progress.
- if you have kidney problems associated with low sodium blood level or you have kidney problems and you are taking certain medicines called diuretics that lower sodium blood levels (such as hydrochlorothiazide, furosemide).
- if you have a thyroid problem (underactive thyroid).
- if you have eye problems such as glaucoma (increased pressure in the eye) or you are unable to empty your bladder (pass urine) completely or partially.
- if you notice symptoms suggestive of hepatitis (inflammation of the liver), such as jaundice (yellowing of skin and eyes), tell your doctor immediately.
- if you experience a change in mental state including seeing or hearing things that other people cannot see or hear (hallucinations), believing things that are not actually true (delusions) or are an elderly patient and experience confusion or agitation, inform your doctor immediately.
- a small number of people being treated with anti-epileptics such as PINOMAZ CR have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- if you are pregnant or suspect you are pregnant, as PINOMAZ CR may cause foetal harm.
- if you are a female of childbearing-age you should use an effective method of contraception throughout your treatment and for 2 weeks after your last dose. If you are taking a hormonal contraceptive (birth control medicine), PINOMAZ CR may render this contraceptive ineffective. Therefore, you should use a different or additional non-hormonal method of contraception while taking this medicine.
- tell your doctor at once if you get irregular vaginal bleeding or spotting.

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- do not stop taking your medicine abruptly as this may lead to sudden worsening of your seizures, your doctor will gradually decrease your dose.
- if you experience poor muscle control that causes clumsy voluntary movements, dizziness, drowsiness, decrease in blood pressure, confusion, calm sedated feeling whilst taking PINOMAZ CR, this may lead to falls.

Other medicines and PINOMAZ CR

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Because of the way that PINOMAZ CR works, it can affect, and be affected by other medicines that you are taking.

It is very important to make sure that your doctor knows all about what else you are taking, including anything that you have bought from a pharmacy or health food shop. It may be necessary to change the dose of some medicines or stop taking them altogether.

Medicines that may increase the effects of PINOMAZ CR include:

- ibuprofen, dextropropoxyphene (anti-inflammatory and pain relief)
- danazol (to treat endometriosis)
- erythromycin, troleandomycin, josamycin, clarithromycin, ciprofloxacin (antibiotics),
- desipramine, fluoxetine, fluvoxamine, nefazodone, paroxetine, trazadone, viloxazine (antidepressants)
- stiripentol, vigabatrin (to treat epilepsy)
- itraconazole, ketoconazole, fluconazole, voriconazole (used to treat fungal infections)
- loratadine, terfenadine (helps with the symptoms of allergies)
- olanzapine (used to treat certain mental/mood conditions such as schizophrenia, bipolar disorder)

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- isoniazid (used to treat tuberculosis)
- ritonavir (used in the treatment of HIV)
- acetazolamide (a water tablet to reduce fluid retention)
- diltiazem (to treat high blood pressure and to control chest pain), verapamil (to prevent chest pain caused by angina as well as irregular heart rhythms)
- cimetidine, omeprazole (to treat indigestion and heartburn, and acid reflux)
- oxybutynin, dantrolene (muscle relaxants)
- ticlopidine (to prevent stroke),
- vitamin B₃ (in high doses) and grapefruit juice.

To avoid unwanted side effects such as dizziness, drowsiness, balance and coordination disorders, double vision, your doctor may adjust the dose of PINOMAZ CR if you are taking any of the following:

- loxapine (to treat the symptoms of schizophrenia)
- quetiapine, valproic acid, valpromide (to treat bipolar disorder - depressive and manic episodes)
- primidone, progabide, brivaracetam (to control seizures)
- valnoctamide (treatment of mania).

Medicines that may decrease the effects of PINOMAZ CR include:

- felbamate, methsuximide, oxcarbazepine, phenobarbitone, phensuximide, phenytoin (used in the treatment of epilepsy)
- primidone (used to treat seizures and/or tremors), clonazepam (used treat anxiety disorders, seizures and several other psychiatric disorders)
- cisplatin or doxorubicin (to treat certain types of cancer)
- rifampicin (used to treat tuberculosis)
- theophylline, aminophylline (asthma medicines)

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- isotretinoin (treatment for acne)
- herbal preparations containing St John's Wort (used for depression and anxiety).

PINOMAZ CR may reduce the effect of certain medicines. Your dose of the following medicines may need to be adjusted:

- buprenorphine, methadone, paracetamol, tramadol (to treat pain and inflammation)
- doxycycline, rifabutin (antibiotics)
- warfarin, rivaroxaban, dabigatran, apixaban, endoxaban (blood thinners to prevent clotting)
- bupropion, citalopram, mianserin, nefazodone, trazodone, imipramine, amitriptyline, nortriptyline, clomipramine (antidepressants)
- aprepitant (to prevent nausea and vomiting after chemotherapy)
- clobazam, clonazepam, ethosuximide, felbamate, lamotrigine, eslicarbazepine, primidone, tiagabine, topiramate, valproic acid, zonisamide, phenytoin (used to treat epilepsy)
- itraconazole, voriconazole (antifungal medicines)
- praziquantel, albendazole (to treat infections of certain parasites)
- imatinib, cyclophosphamide, lapatinib, temsirolimus (to treat cancer)
- clozapine, haloperidol and bromperidol, quetiapine, risperidone, ziprasidone, olanzapine, aripiprazole, paliperidone (to treat mental conditions)
- alprazolam, midazolam (to treat anxiety disorders)
- theophylline (to prevent and treat wheezing, shortness of breath, and chest tightness)
- hormonal contraceptives (alternative contraceptive methods are required),
- felodipine (used to treat high blood pressure), digoxin, Ivabradine (used to treat heart disease)
- simvastatin, atorvastatin, lovastatin, cerivastatin (used to treat high cholesterol levels)

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- prednisolone, dexamethasone (corticosteroids used to lower inflammation)
- ciclosporin, everolimus, tacrolimus, sirolimus (stop your immune system from damaging healthy cells and tissues after organ transplant),
- levothyroxine (to treat an underactive thyroid gland)
- folic acid (type of Vitamin B)
- Taking PINOMAZ CR with monoamine oxidase inhibitors (MAOIs) (used in the treatment of depression and other nervous system disorders such as panic disorder, social phobia), e.g. phenelzine, tranylcypromine and selegeline, is contraindicated (see Do not take PINOMAZ CR).

Your doctor will monitor you closely when taking the following medicines with PINOMAZ CR:

- levetiracetam (used to treat epilepsy)
- isoniazid (used in the treatment of tuberculosis)
- lithium (a mood stabilizer), or metoclopramide (to relieve heartburn and treat ulcers)
- haloperidol (to treat certain mental/mood disorders), thioridazine (to treat schizophrenia)
- hydrochlorothiazide, furosemide (water tablets)
- pancuronium (a muscle relaxant)
- rivaroxaban, dabigatran, apixaban and edoxaban (blood thinners)

Certain blood test results may be affected by PINOMAZ CR.

PINOMAZ CR with food and drink

Do not drink alcohol when you are taking PINOMAZ CR.

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Do not drink grapefruit juice or eat grapefruit since this can increase the effect of PINOMAZ CR.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using PINOMAZ CR.

If you are a woman who is able to have a baby and are not planning a pregnancy, you should use effective contraception during treatment with PINOMAZ CR. This medicine may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking PINOMAZ CR. Should treatment with PINOMAZ CR be discontinued, you should continue using effective contraception for at least two more weeks following discontinuation.

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby. You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy remains well controlled.

Safety of PINOMAZ CR in pregnancy has not been demonstrated.

Taking PINOMAZ CR during pregnancy increases the chance that the baby may have a physical birth abnormality (major congenital malformations).

These abnormalities can develop early in pregnancy, even before you know you are pregnant.

The most common types of major congenital malformations reported for carbamazepine include

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spina bifida (where the bones of the spine are not properly developed); facial and skull malformations including cleft lip/palate; skeletal, heart, urinary tract and sexual organ malformations.

Ask your doctor about taking folic acid when trying for a baby and during pregnancy. Folic acid may lower the general risk of serious physical birth abnormalities that exist with all pregnancies.

If you take PINOMAZ CR during pregnancy, your baby is also at risk for bleeding problems right after birth. Your doctor may give you and your baby medicine to prevent this.

Do not take PINOMAZ CR if you are breastfeeding.

Men may experience infertility problems.

Driving and using machines

Your ability to react may already be impaired due to your medical condition that causes seizures.

In addition, PINOMAZ CR can make you feel dizzy or drowsy, or may cause blurred vision, or you may have a lack of muscular coordination, especially at the start of treatment or when the dose is changed. If you are affected in this way, or if your eyesight is affected, you should not drive or operate machinery.

It is not always possible to predict to what extent PINOMAZ CR 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 PINOMAZ CR affects them.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per 200 mg or 400 mg, that is to say essentially 'sodium-free'.

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3. How to take PINOMAZ CR

Do not share medicines prescribed for you with any other person. Always use PINOMAZ CR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

To treat epilepsy the usual doses are:

Adults:

100 – 200 mg once or twice a day followed by a slow increase to a level of 400 mg twice or three times a day. In some patients 1600 mg a day may be needed, divided in 2 or 3 doses daily.

Children and adolescents:

For children aged 4 years or less, a starting dose of 20-60mg/day, increasing by 20-60mg every second day, has been recommended. For children over the age of 4 years, therapy may begin with 100mg/day, increasing at weekly intervals by 100mg.

Maintenance dosage:

10 to 20 mg /kg per day daily in several divided doses.

Age up to 1 year: 200 mg per day

1 to 5 years: 200 – 400 mg per day

6 to 10 years: 400 – 600 mg per day

11 to 15 years: 600 – 1000 mg per day

>15 years of age: 800 - 1200 mg/day (same as daily dose in adults)

Trigeminal neuralgia

The starting dosage of 200 to 400 mg a day is slowly raised until there is no pain (usually 200 mg 3 to 4 times a day, however it may sometimes be as much as 1600 mg per day). If you are elderly or particularly sensitive a lower starting dose, 100 mg twice daily is recommended.

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Acute mania and maintenance treatment of (bipolar) affective disorders

The usual dosage is approximately 400 to 1 600 mg a day divided over 2 to 3 doses, the usual dosage being 400 – 600 mg given in 2 – 3 divided doses.

Your doctor will tell you exactly how many doses of PINOMAZ CR to take daily.

The dose prescribed by your doctor may be different from those listed above. In this case follow your doctor's instructions.

PINOMAZ CR can be taken either during or after a meal. Swallow the tablets whole with some liquid if necessary.

Your doctor will tell you how long your treatment with PINOMAZ CR will last. Do not stop treatment early because you may experience unwanted adverse effects.

If you have the impression that the effect of PINOMAZ CR is too strong or too weak, tell your doctor or pharmacist.

If you take more PINOMAZ CR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- central nervous system depression (symptoms include reduced heart rate, low breathing rate confusion etc.), feeling disorientated, state of drowsiness, agitation, hallucination, coma, blurred vision, slurred speech, rapid uncontrollable eye movement, poor muscle control, uncontrolled, involuntary muscle movement, increase overactive/underactive muscle reflex responses convulsions/fits, a slowing down of thought and a lowering of physical movements, quick jerking movement that you cannot control, drop in body temperature, dilated pupils, difficulty in breathing, a fast and/or irregular heartbeat, low

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blood pressure, high blood pressure, nausea and a full feeling after little food is eaten, constipation, vomiting, muscle disease called rhabdomyolysis, kidney problems causing less urination and fluid retention, abnormal laboratory test results.

If you forget to take PINOMAZ CR

If you forget to take PINOMAZ CR, take as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and then go on as before. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PINOMAZ CR can have side effects.

Not all side effects reported for PINOMAZ CR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using PINOMAZ CR, please consult your healthcare provider for advice.

If any of the following happens, stop using PINOMAZ CR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

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

- serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, or skin

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peeling accompanied by fever (DRESS - Drug Rash with Eosinophilia and Systemic Symptom)

- mouth ulcers or unexplained bruising or bleeding, sore throat or high temperature, or both, swollen glands or more easily getting infections (signs of lack of white blood cells)
- jaundice (yellowing of the skin and eyes, dark urine, and tiredness), which may be symptoms of liver problems
- darkening of urine (signs of porphyria or hepatitis)
- severe decreased urine output due to kidney disorders, blood in the urine
- severe upper abdominal pain, vomiting, loss of appetite (signs of pancreatitis)
- lethargy, contusion, muscular twitching or significant worsening of convulsions (symptoms that may be linked to low sodium levels in the blood)
- fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light (signs of meningitis)
- muscular stiffness, high fever, altered consciousness, high blood pressure, excessive salivation (signs at neuroleptic malignant syndrome)
- irregular heartbeat, chest pain
- hallucinations, depression, aggression, agitation, restlessness, confusion, delusions (false beliefs)
- multi-organ hypersensitivity disorder (fever, skin rash, joint pain, and abnormalities in blood and liver function tests)
- diarrhoea, abdominal pain/cramping and fever (some of signs of an inflammation of the colon - colitis)
- falling due to dizziness, drowsiness, decrease in blood pressure, confusion
- pain in your joints and muscles, a rash across the bridge of the nose and cheeks and problems with breathing (these may be the signs of a rare reaction known as lupus erythematosus)

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- severe skin reactions including Stevens-Johnson syndrome, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes) often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms) progressing to widespread blistering and peeling of the skin or Toxic Epidermal Necrolysis (TEN) – which is a life-threatening skin condition. Early symptoms include fever and flu-like symptoms. A few days later the skin begins to blister and peel forming painful raw areas
- heart and circulatory problems including blood clot in the lung, swelling and redness along a vein which is extremely tender when touched, often experienced as painful (thrombophlebitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abnormal blood tests results indicating a reduced number of white blood cells which fight infection making it easier to catch infections, changes in the blood including an increased tendency to bruise or bleed
- swelling and discomfort (fluid retention), weight gain
- dizziness, poor muscle control that causes clumsy voluntary movements, sleepiness, headache
- blurred vision, double vision
- nausea, vomiting, dry mouth
- allergic skin reactions or hives which may be severe
- fatigue (tiredness)
- abnormal blood test results.

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Less frequent side effects:

- changes to the composition of the blood including anaemia, decrease in the measure of the bone marrow, disease of the lymph glands
- unusual secretion of breast milk, breast enlargement in men
- folic acid deficiency, decreased appetite, raised levels of ammonia in the blood
- abnormal involuntary movements including tremor, flapping tremor or tics, speech disorders, numbness or tingling in the hands and feet (pins and needles), muscle weakness, memory disorder, altered taste
- cataracts (cloudiness of the lens of the eye, eye pain and swelling, conjunctivitis (pink eye))
- hearing disorders including ringing or buzzing noise, finding many noises unbearable and painfully loud or partial loss of hearing
- high blood pressure (which may make you feel dizzy, with a flushed face, headache, fatigue), low blood pressure (feeling faint, light-headed, dizzy, confused, blurred vision)
- troubled breathing, chest pain, lung inflammation caused by bacterial or viral infection (pneumonia)
- diarrhoea, constipation, stomach pain, swollen tongue, painful swelling and sores inside the mouth
- inflammation of the skin, itching, increased sensitivity of the skin to sunlight, a skin disorder characterised by bull's-eye-shaped lesions, painful skin disorder characterised by tender bumps (nodules) under the skin, alterations in skin pigmentation, rash of purple spots due to small blood vessels leaking blood into the skin, joints, intestines or organs (purpura), acne, excessive sweating, hair loss, increased hair growth on the body and face
- muscle weakness, pain or spasm, osteomalacia (softening of the bones), osteoporosis (medical condition in which the bones become brittle and fragile)

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- itchiness, fatigue, appetite changes, nausea, vomiting, and breathing issues
(tubulointerstitial nephritis), kidney problems, passing urine more frequently or less frequently than is normal for you
- sexual difficulties which may include reduced male fertility, loss of libido or impotence
- abnormal thyroid function tests, eye disorders such as glaucoma, increased blood cholesterol levels.

The following side effects have been reported but the frequency for them to occur is not known:

- reactivation of herpes virus infection (can be serious when immune system is depressed)
- bone marrow failure (rare diseases characterized by an inability to make enough blood)
- sedation, loss of memory
- bone fracture
- sudden skin eruptions that appear on average five days after a medication is started, a skin condition that typically occurs as a single, small, raised plaque, thickened area, or papule (lichenoid keratosis), a condition where the nail plate separates from the nail matrix and nail bed, eventually leading to shedding of the nail
- decrease in the measure of the bone density.

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

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.

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

You can also send an email directly to the company,

pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store PINOMAZ CR

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the HDPE bottle tightly closed.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PINOMAZ CR contains

The active ingredient is carbamazepine.

PINOMAZ CR 100 mg: Each tablet contains carbamazepine 100 mg

PINOMAZ CR 200 mg: Each tablet contains carbamazepine 200 mg

PINOMAZ CR 400 mg: Each tablet contains carbamazepine 400 mg

The other ingredients are:

Tablet cores:

Colloidal silicon dioxide, croscarmellose sodium, ethyl acrylate and methyl methacrylate copolymer dispersion/polyacrylate dispersion, ethyl cellulose aqueous dispersion, hydroxy propyl methyl cellulose, magnesium stearate, microcrystalline cellulose, talc.

Coating:

Instacoat Universal Peach:

Hypromellose 2910, polyethylene glycol 400 & 6000, talc, red iron oxide, titanium dioxide, yellow iron oxide.

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What PINOMAZ CR looks like and contents of the pack

100 mg: Peach coloured, round shaped, biconvex film coated tablets with 'CR 100' debossed on one side and plain on the other side.

200 mg: Peach coloured, round shaped, biconvex film coated tablets with 'CR 200' debossed on one side and plain on the other side.

400 mg: Peach coloured, round shaped, biconvex film coated tablets with 'CR 400' debossed on one side and plain on the other side.

PINOMAZ CR tablets are available

100 mg: 100 or 1000 tablets will be packed in white HPDE bottles with a polypropylene Child resistant (100's) or Continuous thread (1000's) closure.

200 mg: 100 or 1000 tablets will be packed in white HPDE bottles with a polypropylene Child resistant (100's) or Continuous thread (1000's) closure.

400 mg: 100 or 1000 tablets will be packed in white HPDE bottles with a polypropylene Child resistant (100's) or Continuous thread (1000's) closure.

Holder of Certificate of Registration

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Pinomaz 200 mg CR: A59/2.5/0339

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