PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DOLOTRAM 50 solution for injection

DOLOTRAM 100 solution for injection

Tramadol hydrochloride

Sugar free

Read all of this leaflet carefully before you are given DOLOTRAM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What DOLOTRAM is and what it is used for
2. What you need to know before DOLOTRAM is administered
3. How DOLOTRAM is administered
4. Possible side effects
5. How to store DOLOTRAM
6. Contents of the pack and other information.

1. What DOLOTRAM is and what it is used for

Tramadol, the active substance in DOLOTRAM, is a painkiller belonging to the class of the opioids that acts on the central nervous system.

DOLOTRAM is used for the management of moderate to severe pain.

2. What you need to know before DOLOTRAM is administered

DOLOTRAM should not be administered to you:

- If you are hypersensitive (allergic) to tramadol hydrochloride or any of the other ingredients of DOLOTRAM listed in section 6.
- If you have used alcohol, sleeping medication, medicines for anxiety, pain or depression, or narcotic medications within the past few hours.
- If you have asthma or breathing problems (respiratory depression) especially in the presence of cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes) and excessive bronchial secretions.
- If you have previously had head injuries, brain tumour or if you have a condition in which the pressure in your skull has increased.
- If you are taking monoamine oxidase inhibitors (antidepressant medication) or within two weeks of their withdrawal.
- If you are on narcotic withdrawal treatment; DOLOTRAM should not be used as a substitute in withdrawal.
- If you are pregnant or breastfeeding your baby (see section 2, “Pregnancy and breastfeeding”).
- If you have epilepsy not controlled by adequate treatment.
- If you are younger than 12 years of age.
- If you are younger than 18 years of age following tonsillectomy (removal of tonsils) and/or adenoidectomy (removal of adenoids which are located at the back of the nasal cavity).

Warning and precautions

Tell your doctor or health care provider before being administered the injection:

- If you have a history of head injury, epilepsy or other seizure disorder, as the risk of a seizure may increase or the condition can be made worse, especially if the upper dose limit (400 mg) of DOLOTRAM is exceeded.
- If you are in shock (a condition where there is not enough blood flow through the body).
- If you have a history of drug or alcohol addiction or if you think that you are addicted to other

pain relievers (opioids).

- If you have a metabolic disorder; or if you are also using certain medicines to treat migraine headaches, muscle spasms, depression, mental illness, or nausea and vomiting.
- If you are sensitive to opioid pain relievers.
- If you are addicted to other opioids, as DOLOTRAM is not a suitable substitute to suppress withdrawal symptoms.

Substance abuse and dependence:

DOLOTRAM can lead to psychological and physical dependence or addiction in some people, especially with long-term use

The dose needed to achieve the desired effect may increase with time. If you find that treatment with DOLOTRAM is less effective after long-term use, it could be a sign that you have developed tolerance. If this happens, speak to your doctor about your treatment.

DOLOTRAM should be used with caution, and only for short periods under strict medical supervision, in patients who are addicted to other opioid painkillers.

Increasing the dose of DOLOTRAM can make you more sensitive to pain. If this happens, you need to speak to your health care provider about your treatment.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to DOLOTRAM if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Withdrawal symptoms

You may experience withdrawal symptoms if treatment with DOLOTRAM is suddenly stopped. Withdrawal symptoms can include agitation, anxiety, nervousness, difficulty sleeping, restlessness, tremor (uncontrolled shaking) and gastrointestinal (stomach) symptoms.

Your doctor will discuss with you how to gradually reduce your dose of DOLOTRAM before stopping.

Ultra-rapid metabolisers:

DOLOTRAM works by being converted (metabolised) into its active component. If you convert (metabolise) DOLOTRAM to this active component more rapidly and completely than other patients, you are known as an ultra-rapid metaboliser. If you are an ultra-rapid metaboliser you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking this medicine and consult your doctor immediately.

Hyponatraemia:

You may experience low levels of sodium in the blood (hyponatraemia) while using DOLOTRAM. Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps, and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while using DOLOTRAM, consult your doctor immediately.

Sleep-related breathing disorders:

DOLOTRAM contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnoea (shallow/pause of breathing during sleep) and sleep related hypoxaemia (low level of oxygen in the blood). The risk

of experiencing central sleep apnoea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnoea.
If you use DOLOTRAM together with sedative medicines (such as benzodiazepines or related medicines), the risk of feeling extremely drowsy or experiencing a difficulty in breathing may occur (see section 2, “Other medicines and DOLOTRAM”).
Talk to your doctor or pharmacist if you experience any of the following symptoms while receiving DOLOTRAM: Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, consult your doctor, who will decide if you need to take hormone supplement.

Serotonin syndrome:

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having received tramadol hydrochloride (the active ingredient of DOLOTRAM) in combination with certain antidepressants or tramadol hydrochloride alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4).

Other:

Special care should be taken with DOLOTRAM if you have liver or kidney disease.

Children and adolescents:

DOLOTRAM is not indicated for children below the age of 12 years or in children younger than 18 years following tonsillectomy (removal of tonsils) and/or adenoidectomy (removal of adenoids which are located at the back of the nasal cavity)(see section 2, “DOLOTRAM should not be administered to you”).

Other medicines and DOLOTRAM

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Medicines known to influence the effect of tramadol hydrochloride (as in DOLOTRAM) are:

- Carbamazepine (used for seizures).
- Quinidine (used for heart rhythm disorders) or other CYP2D6 inhibitors such as paroxetine (used for depression).
- Alcohol.
- Ketoconazole (used for fungal infections).
- Erythromycin (used for bacterial infections).
- Monoamine oxidase inhibitors (a type of antidepressant), or if you have used this medication within 14 days of stopping such treatment.
- Ondansetron (used to prevent feeling or being sick).
- If you are taking certain antidepressants. DOLOTRAM may interact with these medicines and you may experience serotonin syndrome (see section 4).
- Medicines that prevent blood clotting, such as warfarin; the dose of these medicines may need to be reduced, otherwise there could be an increased risk of potentially serious bleeding.

Pregnancy, breastfeeding and Fertility

DOLOTRAM should not be used if you are pregnant or breastfeeding your baby. It may harm your baby.

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

Driving and using machines:

Do not drive or operate machinery while using DOLOTRAM.

DOLOTRAM may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. Do not drive a car or other vehicle, do not use electric tools or operate machinery until you are sure how DOLOTRAM affects you.

3. How DOLOTRAM will be administered

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

You will not be expected to give yourself DOLOTRAM. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with DOLOTRAM will last. If you have the impression that the effect of DOLOTRAM is too strong or too weak, tell your doctor or pharmacist.

Your doctor will adjust your dosage according to the intensity of your pain and your individual pain sensitivity. The lowest pain-relieving dose will be used. A total daily dose of DOLOTRAM should not exceed 400 mg tramadol.

Adults and children older than 12 years of age:

The usual dose is 50 or 100 mg given 4 to 6 hourly as an intravenous, intramuscular or subcutaneous injection.

The doctor may change your dose if you are an elderly patient (above 75 years) or if you suffer from liver and/or kidney insufficiency.

If you receive more DOLOTRAM than you should:

Since a health care provider will administer DOLOTRAM, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive DOLOTRAM:

Since a health care provider will administer DOLOTRAM, it is unlikely that the dose will be missed.

4. Possible side effects

DOLOTRAM can have side effects.

Not all side effects reported for DOLOTRAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DOLOTRAM, please consult your doctor, pharmacist or other health care provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips and 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 DOLOTRAM. 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:

- Seizure (convulsions).
- Weak or shallow breathing.
- Agitation.
- Hallucinations.
- Fever.
- Fast heart rate.
- Overactive reflexes.
- Loss of coordination, fainting.
- Severe skin reaction, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.
- Sore throat.

- Burning in your eyes.
- Serotonin syndrome. You may experience symptoms such as muscular rigidity, agitation, hallucinations, coma, fever, increase in heart rate, unstable blood pressure, involuntary twitching, lack of coordination, nausea, vomiting, diarrhoea.

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

Tell your doctor if you notice any of the following:

Frequent:

- Headache.
- Dizziness.
- Drowsiness.
- Feeling tired.
- Constipation.
- Diarrhoea.
- Nausea.
- Vomiting.
- Stomach pain.
- Dry mouth.
- Sweating.
- Flushing (warmth, redness, or tingly feeling).

Less frequent:

- Feeling nervous or anxious.
- Itching.
- Rash.
- Low blood sugar levels.
- Changes in appetite.
- Heartburn.
- Trembling.

- Nightmares.
- Disturbed sleep patterns.
- Difficulty or pain passing water.
- Muscle weakness.
- Blurred vision.
- Withdrawal syndrome.

Frequency unknown:

- Hiccups.
- Confusion.
- Delusions.
- Despersonalisation-derealisation.
- Paranoia.
- Drug dependence.

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

Reporting of side effects:

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

5. How to store DOLOTRAM

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Return all unused medicine to your pharmacist.

Do not use after the expiry date printed on the label.

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

6. Contents of the pack and other information

What DOLOTRAM contains:

The active substance is tramadol hydrochloride.

DOLOTRAM 50: Each ampoule contains 50 mg tramadol hydrochloride as active ingredient.

DOLOTRAM 100: Each ampoule contains 100 mg tramadol hydrochloride as active ingredient.

The other ingredients are sodium hydroxide and water for injection.

What DOLOTRAM looks like and contents of the pack:

DOLOTRAM 50: A clear colourless solution filled in 1 mL clear glass OPC ampoule with a yellow ring and blue dot.

DOLOTRAM 100: A clear colourless solution in 2 mL clear glass OPC ampoule with a maroon ring and blue dot.

Pack size:

5 ampoules are packed in a plastic tray per carton.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1, Roodepoort

Johannesburg 1724

Tel. no.: 011 495 0100

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

DOLOTRAM 50 oplossing vir inspuiting

DOLOTRAM 100 oplossing vir inspuiting

Tramadolhidrochloried

Suikervry

Lees hierdie hele inligtingsblad noukeurig deur voordat DOLOTRAM aan jou toegedien word.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.

Wat is in hierdie inligtingsblad:

1. Wat is DOLOTRAM en waarvoor word dit gebruik
2. Wat jy moet weet voordat DOLOTRAM toegedien word
3. Hoe DOLOTRAM toegedien sal word
4. Moontlike newe-effekte
5. Hoe om DOLOTRAM te bewaar
6. Inhoud van die verpakking en ander inligting.

1. Wat is DOLOTRAM en waarvoor word dit gebruik

Tramadol, die aktiewe bestanddeel in DOLOTRAM, is ’n pynverligter wat aan die klas van die opioïede behoort wat op die sentrale senuweestelsel inwerk.

DOLOTRAM word gebruik vir die beheer van matige tot erge pyn.

2. Wat jy moet weet voordat DOLOTRAM toegedien word

DOLOTRAM moenie aan jou toegedien word nie:

- Indien jy hipersensitief (allergies) vir tramadolhidrochloried of vir enige van die ander bestanddele van DOLOTRAM is, gelys by afdeling 6.
- Indien jy binne die afgelope paar uur alkohol, slaapmedikasie, medisyne vir angstigheid, pyn of depressie, of narkotiese medikasie gebruik het.
- Indien jy asma of asemhalingsprobleme (respiratoriese onderdrukking), veral in die teenwoordigheid van sianose (die vel, naels, lippe of rondom die oë lyk blouerig of gryserig) en oormatige brongiale afskeiding het.
- Indien jy voorheen hoofbeserings of ’n breingewas gehad het, of indien jy aan ’n toestand ly waar die druk binne-in jou skedel verhoog is.
- Indien jy monoamienoksidase-inhibeerders (antidepressantmedikasie) gebruik of binne twee weke ná die onttrekking daarvan.
- Indien jy behandeling ontvang vir onttrekking van narkotiese middels; DOLOTRAM moenie as ’n plaasvervanger by middelonttrekking gebruik word nie.
- Indien jy swanger is of jou baba borsvoed (sien afdeling 2, “Swangerskap en borsvoeding”).
- Indien jy epilepsie het, wat nie voldoende met behandeling beheer word nie.
- Indien jy jonger as 12 jaar is.
- Indien jy jonger as 18 jaar is, ná ’n tonsillektomie (verwydering van mangels) en/of adenoïdektomie (verwydering van adenoïede, wat agter in die neusholte voorkom).

Waarskuwings en voorsorgmaatreëls:

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting aan jou toegedien word:

- Indien jy ’n geskiedenis van hoofbesering, epilepsie of ’n ander toevalversteuring het,

aangesien die risiko vir ’n toeval groter kan wees of die toestand erger gemaak kan word, veral indien die boonste limiet van die dosis (400 mg) van DOLOTRAM oorskry word.

- Indien jy in skok is (’n toestand waar bloedvloei deur die liggaam onvoldoende is).
- Indien jy ’n geskiedenis van dwelm- of alkoholverslawing het, of jy dink dat jy aan ander pynstillers (opioïede) verslaaf is.
- Indien jy ’n metaboliese versteuring het; of indien jy ook sekere medisyne gebruik om skeelhoofpyn (migraine), spierspasmas, depressie, geestesiekte, of naarheid en braking te behandel.
- Indien jy sensitief is vir opioïed-pynverligters
- Indien jy verslaaf is aan ander opioïede, aangesien DOLOTRAM nie ‘n geskikte plaasvervanger is om onttrekkingsimptome te onderdruk nie.

Substansmisbruik en -afhanklikheid:

DOLOTRAM kan tot psigologiese en fisieke afhanklikheid of verslawing by sommige persone lei, veral met langtermyngebruik.

Die dosis wat nodig is om die verlangde effek te bereik, mag toeneem oor tyd. As jy vind dat behandeling met DOLOTRAM minder doeltreffend is ná langtermyngebruik, kan dit ‘n teken wees dat jy toleransie bereik het. As dit gebeur, moet jy die behandeling met jou dokter bespreek.

By pasiënte wat aan ander opioïedpynstillers verslaaf is, moet DOLOTRAM met omsigtigheid en slegs vir kort tydperke onder streng mediese toesig gebruik word.

Verhoging van die dosis van DOLOTRAM kan jou meer sensitief vir pyn maak. Indien dit gebeur, moet jy jou behandeling met jou gesondheidsorgverskaffer bespreek.

Die risiko om afhanklik of verslaaf te raak varieer van persoon tot persoon. Jy mag ‘n groter risiko hê om afhanklik te raak van of verslaaf te raak aan DOLOTRAM, as:

- Jy of enigeen in jou familie al ooit alkohol, voorskrifmedisyne of onwettige substanse

("verslawing") misbruik het of afhanklik daarvan was nie.

- Jy 'n roker is
- Jy al ooit probleme met jou gemoed (depressie, angstigheid of 'n persoonlikheidsversteuring) of deur 'n psigiater behandel is vir ander geestessiektes het of gehad het.

Onttrekkingsimptome

Jy mag onttrekkingsimptome ervaar as behandeling met DOLOTRAM skielik gestaak word. Onttrekkingsimptome kan agitasie, angstigheid, senuweeagtigheid, probleme om te slaap, rusteloosheid, bewerigheid (ongekontroleerde skudding) en gastro-intestinale (maag) simptome insluit.
Jou dokter sal dit met jou bespreek om geleidelik jou dosis van DOLOTRAM te verlaag voordat dit gestaak word.

Ultra-vinnige metaboliseerders:

DOLOTRAM werk deurdat dit omgeskakel (gemetaboliseer) word na die aktiewe komponent daarvan. Indien jy DOLOTRAM vinniger en meer volledig na hierdie aktiewe komponent omskakel (metaboliseer) as ander pasiënte, staan jy bekend as 'n ultra-vinnige metaboliseerder. Indien jy 'n ultra-vinnige metaboliseerder is, is dit meer waarskynlik dat jy ernstige newe-effekte sal hê, soos asemhalingsprobleme, met stadige of vlak asemhaling. Indien jy hierdie soort newe-effekte ondervind, hou op om hierdie medisyne te gebruik en raadpleeg onmiddellik jou dokter.

Hiponatremie:

Jy kan lae natriumvlakke in jou bloed hê (hiponatremie) terwyl DOLOTRAM gebruik word. Simptome van 'n lae natriumvlak kan naarheid en braking, hoofpyne, verwardheid, uiterse moegheid, rusteloosheid, prikkelbaarheid, spierswakheid, -spasmas of -krampe en toevalle

insluit. Bejaarde pasiënte en pasiënte wat ander medisyne neem wat natrium in die bloed verlaag, het die grootste risiko om hierdie newe-effek te ondervind. Indien jy enige van hierdie simptome ervaar terwyl DOLOTRAM gebruik word, raadpleeg onmiddellik jou dokter.

Slaapverwante asemhalingsversteurings:

DOLOTRAM bevat ’n aktiewe bestanddeel wat aan die opioïed-groep behoort. Opioïede kan slaapverwante asemhalingsversteurings veroorsaak, byvoorbeeld sentrale slaapapnee (vlak asemhaling of onderbreking in asemhaling tydens slaap) en slaapverwante hipoksemie (lae vlak van suurstof in die bloed). Die risiko om sentrale slaapapnee te ervaar, hang af van die dosis van opioïede. Jou dokter mag dit oorweeg om jou totale opioïeddosis te verlaag indien jy sentrale slaapapnee ondervind.

Indien jy DOLOTRAM saam met kalmeermiddels (soos bensodiasepiene of verwante medisyne) gebruik, mag daar ’n risiko wees dat jy buitensporig lomerig voel of probleme met asemhaling kan voorkom (sien afdeling 2, “Ander medisyne en DOLOTRAM”).

Sê vir jou dokter of apteker indien jy enige van die volgende simptome ervaar terwyl jy DOLOTRAM ontvang: buitensporige moegheid, aptytverlies, erge buikpyn, naarheid, braking of lae bloeddruk. Dit mag daarop dui dat jy adrenale ontoereikendheid (lae kortisolvlakke) het. Indien jy hierdie simptome het, raadpleeg jou dokter, wat sal besluit of dit nodig is dat jy ’n hormoonaanvulling neem.

Serotoniensindroom:

Daar is ’n klein risiko dat jy ’n sogenaamde serotoniensindroom kan ervaar nadat jy tramadolhidrochloried (die aktiewe bestanddeel van DOLOTRAM) in kombinasie met sekere antidepressante of tramadolhidrochloried alleen, ontvang het. Verkry onmiddellik mediese advies indien jy enige van die simptome verwant aan hierdie ernstige sindroom ervaar (sien

afdeling 4).

Ander:

Spesiale sorg moet met DOLOTRAM geneem word indien jy lewer- of niersiekte het.

Kinders en adolessente:

DOLOTRAM word nie by kinders jonger as 12 jaar, of by kinders wat jonger as 18 jaar is ná ’n tonsillektomie (verwydering van mangels) en/of adenoïdektomie (verwydering van adenoïede, wat agter in die neusholte voorkom) aangedui nie (sien afdeling 2, “DOLOTRAM moenie aan jou toegedien word nie”).

Ander medisyne en DOLOTRAM:

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Medisynes wat bekend is dat dit die effek van tramadolhidrochloried (soos in DOLOTRAM) beïnvloed, is:

- Karbamasepien (gebruik vir toevalle).
- Kinidien (gebruik vir versteurings van hartritme) of ander CYP2D6-inhibeerdes soos paroksetien (gebruik vir depressie).
- Alkohol.
- Ketokonasool (gebruik vir swaminfeksie).
- Eritromisien (gebruik vir bakteriële infeksie).
- Monoamienoksidase-inhibeerdes (’n soort antidepressant), of binne 14 dae nadat jy behandeling met hierdie medikasie gestaak het.
- Ondansetron (gebruik om naarheid en braking te voorkom).

- Indien jy sekere antidepressante neem. DOLOTRAM mag wisselwerking met hierdie medisyne hê en jy mag serotoniensindroom ervaar (sien afdeling 4).
- Medisynes wat bloedstolling voorkom, soos warfarien; dit mag nodig wees om die dosis van hierdie medisyne te verlaag, andersins kan daar ’n verhoogde risiko van potensieel ernstige bloeding wees.

Swangerskap, borsvoeding en vrugbaarheid

DOLOTRAM behoort nie gebruik te word indien jy swanger is of jou baba borsvoed nie. Dit mag skadelik wees vir jou baba.

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy DOLOTRAM ontvang.

Bestuur en die gebruik van masjinerie:

Moenie ’n voertuig bestuur of masjinerie hanteer terwyl jy DOLOTRAM gebruik nie.
DOLOTRAM kan lomerigheid, duiseligheid en dowwe visie veroorsaak en sodoende jou reaksies belemmer. Moenie ’n voertuig bestuur, elektriese gereedskap gebruik of masjinerie hanteer totdat jy seker is hoe DOLOTRAM jou affekteer nie.

3. Hoe DOLOTRAM toegedien sal word

Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Daar sal nie van jou verwag word om DOLOTRAM aan jouself toe te dien nie. Dit sal aan jou toegedien word deur ’n persoon wat gekwalifiseerd is om dit te doen.

Jou dokter sal jou inlig oor hoe lank jou behandeling met DOLOTRAM sal duur. Indien jy die indruk kry dat die uitwerking van DOLOTRAM te sterk of te swak is, bespreek dit met jou

dokter of apteker.

Jou dokter sal jou dosering aanpas na gelang van die intensiteit van jou pyn en jou individuele sensitiwiteit vir pyn. Die laagste dosis wat jou pyn sal verlig, sal gebruik word. Die totale daaglikse dosis van DOLOTRAM moet nie 400 mg tramadol oorskry nie.

Volwassenes en kinders ouer as 12 jaar:

Die gebruiklike dosis is 50 of 100 mg elke 4 tot 6 uur toegedien as ’n binneaarse, binnespierse of onderhuidse inspuiting.

Die dokter mag jou dosis aanpas indien jy ’n bejaarde persoon is (ouer as 75 jaar) of indien jy aan lewer- en/of nierontoereikendheid ly.

Indien jy meer DOLOTRAM ontvang as wat jy behoort te kry:

Aangesien ’n gesondheidsorgverskaffer DOLOTRAM sal toedien, sal hy/sy die dosis beheer. In geval van oordosering, sal jou dokter egter die oordosering bestuur.

Indien jy vergeet om DOLOTRAM te ontvang:

Aangesien ’n gesondheidsorgverskaffer DOLOTRAM sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte

DOLOTRAM kan newe-effekte hê.

Nie alle newe-effekte wat vir DOLOTRAM aangemeld is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy DOLOTRAM ontvang, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer.

Indien enige van die volgende simptome voorkom, hou op om DOLOTRAM te ontvang en sê

dadelik vir jou dokter of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.
- Uitslag of gejeuk.
- Floute.

Hierdie is almal baie ernstige newe-effekte. Jy mag ’n ernstige allergiese reaksie teen DOLOTRAM gehad het as jy dit het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê dadelik vir jou dokter of gaan na die noodvalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

- Toevalle (konvulsies).
- Swak of vlak asemhaling.
- Agitasie.
- Hallusinasies.
- Koors.
- Vinnige hartspoed.
- Ooraktiewe reflekse.
- Koördinasieverlies, floute.
- Hewige velreaksie, pynlike vel, gevolg deur ’n rooi of pers veluitslag wat versprei (veral in die gesig en bolyf) en blaasvorming en afskilfering veroorsaak.
- Seer keel.
- Jou oë brand.
- Serotoniensindroom. Jy mag simptome soos spierrigiditeit, agitasie, hallusinasies, koma, koors, versnelde harttempo, onstabiele bloeddruk, onwillekeurige spiertrekkings, gebrek aan koördinasie, naarheid, braking en diarree ondervind.

Hierdie is almal ernstige newe-effekte. Jy mag dringend mediese bystand nodig hê.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Hoofpyn.
- Duiseligheid.
- Lomerigheid.
- Moegheid.
- Hardlywigheid.
- Diarree.
- Naarheid.
- Braking.
- Maagpyn.
- Droë mond.
- Sweet.
- Blosing (warm gevoel, rooiheid, of ’n tintelende gevoel).

Newe-effekte wat minder dikwels voorkom:

- Voel senuweeagtig of angstig.
- Gejeuk.
- Uitslag.
- Lae bloedsuikervlakke.
- Gewysigde eetlus.
- Sooibrand.
- Bewerigheid.
- Nagmerries.
- Versteurde slaappatrone.
- Sukkel om urine te laat.

- Spierswakheid.
- Dowwe visie.
- Onttrekkingsindroom.

Frekwensie onbekend:

- Hik.
- Verwardheid.
- Delusies.
- Despersonalisasie-derealisasie.
- Paranoia.
- Substansafhanklikheid.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad gelys word nie, lig asseblief jou dokter of apteker daarvan in.

Aanmelding van newe-effekte:

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org wat aanlyn op SAHPRA se webblad beskikbaar is. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van DOLOTRAM te verskaf.

5. Hoe om DOLOTRAM te bewaar

BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Bewaar by of onder 25 °C.

Neem alle ongebruikte medisyne terug na jou apteker toe.

Moenie gebruik ná die vervaldatum wat op die etiket gedruk is nie.

Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat DOLOTRAM bevat:

Die aktiewe bestanddeel is tramadolhidrochloried.

DOLOTRAM 50: Elke ampule bevat 50 mg tramadolhidrochloried as aktiewe bestanddeel.

DOLOTRAM 100: Elke ampule bevat 100 mg tramadolhidrochloried as aktiewe bestanddeel.

Die ander bestanddele is natriumhidroksied en water vir inspuiting.

Hoe DOLOTRAM lyk en inhoud van die verpakking:

DOLOTRAM 50: ’n Helder, kleurlose oplossing in ’n 1 mL helder glas OPC-ampule met ’n geel ring en ‘n blou kol.

DOLOTRAM 100: ’n Helder, kleurlose oplossing in ’n 2 mL helder glas OPC-ampule met ’n maroen ring en ‘n blou kol.

Verpakkingsgrootte: 5 ampulle word per karton in ’n plastiekbakkie verpak.

Houer van registrasiesertifikaat:

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill Uitbr.1, Roodepoort

Johannesburg 1724

Tel: 011 495 0100

Hierdie inligtingsblad is laas hersien in:

24 Januarie 2025

Registrasienommers:

DOLOTRAM 50: 36/2.9/0337

DOLOTRAM 100: 36/2.9/0338

Datum van registrasie:

12 November 2004

Namibië se registrasiebsonderhede:

Skeduleringstatus**:** NS3

DOLOTRAM® 50: 06/2.9/0170

DOLOTRAM® 100: 06/2.9/0171