Bijsluiter: informatie voor de patiënt

Dolten retard 50 mg tabletten met verlengde afgifte
Dolten retard 100 mg tabletten met verlengde afgifte
Dolten retard 150 mg tabletten met verlengde afgifte

tapentadol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dolten retard is and what it is used for

Tapentadol, the active substance in Dolten retard , is a strong painkiller which belongs to the class of opioids. Dolten retard is used for the treatment of severe chronic pain in adults that can only be adequately managed with an opioid painkiller.

2. What you need to know before you take Dolten retard

Do not take Dolten retard
- if you are allergic to tapentadol or any of the other ingredients of this medicine (listed in section 6).
- if you have asthma or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia)
- if you have paralysis of the gut
- if you have acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions) (see “Other medicines and Dolten retard ”)

Warnings and precautions
Talk to your doctor or pharmacist before taking Dolten retard if you
- have slow or shallow breathing,
- suffer from increased pressure in the brain or disturbed consciousness up to coma,
- have had a head injury or brain tumors,
- suffer from a liver or kidney disease (see “How to take Dolten retard ”),
- suffer from a pancreatic or biliary tract disease, including pancreatitis,
- are taking medicines referred to as mixed opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-opioid agonists (e.g., buprenorphine).
- have a tendency towards epilepsy or fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase.

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

This medicine contains tapentadol which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Dolten retard , it is important that you consult your doctor. Use (even at therapeutic doses) may lead to physical dependence, which may result in you suffering withdrawal effects and a recurrence of your problems if you suddenly stop taking this medicine treatment.

Sleep-related breathing disorders
Dolten retard can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Dolten retard
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The risk of side effects increases if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take tapentadol at the same time. Your doctor will tell you whether tapentadol is suitable for you.

Concomitant use of tapentadol and sedative medicines such as benzodiazepines or related drugs (certain sleeping pills or tranquillizers (e.g., barbiturates) or pain relievers such as opioids, morphine and codeine (also as cough medicine), antipsychotics, H1-antihistamines, alcohol) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However, if your doctor does prescribe tapentadol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening. Please tell your doctor if you are taking gabapentin or pregabalin or any sedative medicines and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

If you are taking a type of medicine that affects serotonin levels (e.g., certain medicines to treat depression), speak to your doctor before taking tapentadol as there have been cases of "serotonin syndrome". Serotonin syndrome is a rare, but life-threatening condition. The signs include involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension and body temperature above 38°C. Your doctor may advise you on this.

Taking tapentadol together with other types of medicines referred to as mixed mu-opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-opioid agonists (e.g., buprenorphine) has not been studied. It is possible that tapentadol will not work as well if given together with one of these medicinal products. Tell your doctor in case you are currently treated with one of these medicinal products.

Taking tapentadol together with strong inhibitors or inducers (e.g., rifampicin, phenobarbital, St John's Wort) of certain enzymes that are necessary to eliminate tapentadol from your body, may influence how well tapentadol works or may cause side effects, especially when this other medication is started or stopped. Please keep your doctor informed about all medicines you are taking. Tapentadol should not be taken together with MAO inhibitors (certain medicines for the treatment of depression). Tell your doctor if you are taking MAO inhibitors or have taken these during the last 14 days.

Dolten retard with food, drink and alcohol
Do not drink alcohol whilst taking tapentadol because some side effects such as drowsiness may be increased. Food does not influence the effect of this medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take these tablets:
- if you are pregnant, unless your doctor has instructed you to do so, if used over prolonged periods during pregnancy, tapentadol may lead to withdrawal symptoms in the newborn baby, which might be life-threatening for the new-born if not recognized and treated by a doctor.
- during childbirth because it could lead to dangerously slow or shallow breathing (respiratory depression) in the new-born,
- during breast-feeding, because it may be excreted in the breast milk.

Driving and using machines
Tapentadol may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen when you start taking tapentadol, when your doctor changes your dosage or when you drink alcohol or take tranquillizers. Please ask your doctor whether it is permitted to drive a car or use machines.

Dolten retard contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dolten retard

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will adjust the dosage according to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken.

Use in adults
The recommended dose is 1 tablet every 12 hours. Total daily doses of Dolten retard greater than 500 mg tapentadol are not recommended. Your doctor may prescribe a different, more appropriate dose or interval of dosing, if this is necessary for you. If you feel that the effect of these tablets is too strong or too weak, talk to your doctor or pharmacist.

Use in elderly patients
In elderly patients (above 65 years) usually no dose adjustment is necessary. However, the excretion of tapentadol may be delayed in some patients of this age group. If this applies to you, your doctor may recommend a different dosage regimen.

Use in patients with liver and kidney disease (insufficiency)

Patients with severe liver problems should not take these tablets. If you have moderate problems, your doctor will recommend a different dosage regimen. In case of mild liver problems, a dosage adjustment is not required.
Patients with severe kidney problems should not take these tablets. In case of mild or moderate kidney problems, a dosage adjustment is not required.

Use in children and adolescents
Dolten retard is not suitable for children and adolescents below the age of 18 years.

How and when should you take Dolten retard ?
Dolten retard is for oral use.
Always swallow the tablets whole, with sufficient liquid.
Don't chew it, break it or crush it – this could lead to overdosing, because the drug will be released into your body too quickly. You may take the tablets on an empty stomach or with meals.
The empty shell of the tablet may not be digested completely and thus be seen in stool. This should not worry you, since the drug (active substance) of the tablet has already been absorbed in your body and what you see is just the empty shell.

How long should you take Dolten retard ?
Do not take the tablets for longer than your doctor has told you.

If you take more Dolten retard than you should
After taking very high doses, the following may be experienced: pin-point pupils, vomiting, drop in blood pressure, fast heartbeat, collapse, disturbed consciousness or coma (deep unconsciousness), epileptic fits, dangerously slow or shallow breathing or stopping breathing may occur.
If this happens a doctor should be called immediately!

If you forget to take Dolten retard
If you forget to take the tablets, your pain is likely to return. Do not take a double dose to make up for a forgotten dose, simply continue taking the tablets as before.

If you stop taking Dolten retard
If you interrupt or stop treatment too soon, your pain is likely to return. If you wish to stop treatment, please tell your doctor first before stopping treatment.
Generally, there will be no after-effects when treatment is stopped, however, on uncommon occasions, people who have been taking the tablets for some time may feel unwell if they abruptly stop taking them. Symptoms may be:
- restlessness, watery eyes, runny nose, yawning, sweating, chills, muscle pain and dilated pupils,
- irritability, anxiety, backache, joint pain, weakness, abdominal cramps, difficulty in sleeping, nausea, loss of appetite, vomiting, diarrhea, and increases in blood pressure, breathing or heart rate.

If you experience any of these complaints after stopping treatment, please consult your doctor.
You should not suddenly stop taking this medicine unless your doctor tells you to. If your doctor wants you to stop taking your tablets he/she will tell you how to do this, this may include a gradual reduction of the dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects or symptoms to look out for and what to do if you are affected:
This medicine may cause allergic reactions. Symptoms may be wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching, especially those covering your whole body.

Another serious side effect is a condition where you breathe more slowly or weakly than expected. It mostly occurs in elderly and weak patients.

If you are affected by these important side effects contact a doctor immediately.

Other side effects that may occur:
Very common (may affect more than 1 in 10 people): nausea, constipation, dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people): decreased appetite, anxiety, depressed mood, sleep problem, nervousness, restlessness, disturbance in attention, trembling, muscle twitches, flushing, shortness of breath, vomiting, diarrhoea, indigestion, itching, increased sweating, rash, feeling of weakness, fatigue, feeling of body temperature change, mucosal dryness, accumulation of water in the tissue (oedema).

Uncommon (may affect up to 1 in 100 people): allergic reaction to medicines (including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock), weight loss, disorientation, confusion, excitability (agitation), perception disturbances, abnormal dreams, euphoric mood, depressed level of consciousness, memory impairment, mental impairment, fainting, sedation, balance disorder, difficulty in speaking, numbness, abnormal sensations of the skin (e.g. tingling, prickling), abnormal vision, faster heart-beat, slower heart-beat, palpitations, decreased blood pressure, abdominal discomfort, hives, delay in passing urine, frequent urination, sexual dysfunction, drug withdrawal syndrome (see "If you stop taking Dolten retard "), feeling abnormal, irritability.

Rare (may affect up to 1 in 1,000 people): drug dependence, thinking abnormal, epileptic fit, near fainting, coordination abnormal, dangerously slow or shallow breathing (respiratory depression), impaired gastric emptying, feeling drunk, feeling of relaxation.

Not known: Delirium.

In general, the likelihood of having suicidal thoughts and behaviour is increased in patients suffering from chronic pain. In addition, certain medicines for the treatment of depression (which have an impact on the neurotransmitter system in the brain) may increase this risk, especially at the beginning of treatment.
Although tapentadol also affects neurotransmitters, data from human use of tapentadol do not provide evidence for an increased risk.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dolten retard

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dolten retard contains

- The active substance is tapentadol.
  Each prolonged release tablet contains 58.24mg tapentadol hydrochloride equivalent to 50 mg tapentadol.
  Each prolonged release tablet contains 116.48mg tapentadol hydrochloride equivalent to 100 mg tapentadol.
  Each prolonged release tablet contains 174.72mg tapentadol hydrochloride equivalent to 150 mg tapentadol.
- The other ingredients are in *tablet core*: Silicified microcrystalline cellulose, Hypromellose E464, Magnesium stearate E470b; *film coating*: Hypromellose E464, Lactose monohydrate, Talc E553b, Macrogol 6000 E1521, Titanium dioxide E171, Propylene glycol E1520, Iron oxide red E172 (*50 mg and 150 mg*), Iron oxide yellow E172

What Dolten retard looks like and contents of the pack

50 mg: Peach, oval shaped, biconvex, film-coated tablets, debossed "D" on one side and plain on the other side with dimensions 15 x 7mm
100 mg: Yellow, oval shaped, biconvex, film-coated tablets debossed 'C' on one side and plain on the other side with dimensions 15 x 7mm
150 mg: Brown, oval shaped, biconvex, film-coated tablets, debossed "E" on one side and plain on the other side with dimensions 15 x 7mm

Clear PVC/PE/PVDC-aluminium blisters.
Packs of 7, 10, 14, 20, 24, 28, 30, 40, 50, 54, 56, 60, 90, 100 prolonged-release tablets.
Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder
Medochemie Ltd
1-10 Constantinoupoleos street
3011 Limassol
Cyprus

Fabrikant
Medochemie Ltd – Factory AZ
Agios Athanassios Industrial Area, Michail Irakleous 2, Agios Athanassios
4101 Limassol
Cyprus

Dit medicijn is in het register ingeschreven onder:

Dolten retard 50 mg tabletten met verlengde afgifte	RVG 130561
Dolten retard 100 mg tabletten met verlengde afgifte	RVG 130562
Dolten retard 150 mg tabletten met verlengde afgifte	RVG 130563

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland	Dolten retard 50 mg tabletten met verlengde afgifte Dolten retard 100 mg tabletten met verlengde afgifte Dolten retard 150 mg tabletten met verlengde afgifte
Cyprus	Dolten retard 50 mg δισκία παρατεταμένης αποδέσμευσης Dolten retard 100 mg δισκία παρατεταμένης αποδέσμευσης Dolten retard150 mg δισκία παρατεταμένης αποδέσμευσης
Tsjechië	DOLUPREN
Estland	Tapemed retard
Griekenland	Dolupren®
Malta	Dolten retard 50 mg prolonged-release tablets Dolten retard 100 mg prolonged-release tablets Dolten retard 150 mg prolonged-release tablets
Slowakije	DOLTEN RETARD 50 mg DOLTEN RETARD 100 mg DOLTEN RETARD 150 mg

Deze bijsluiter is voor het laatst goedgekeurd in december 2023.