

Marol 100 mg, 150 mg and 200 mg
Prolonged Release Tablets
(Tramadol hydrochloride)

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

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1

What Marol Tablets are and what they are used for

The name of your medicine is **Marol 100 mg, 150 mg or 200 mg Prolonged-release Tablets**.

Each prolonged release tablet contains 100 mg, 150 mg or 200 mg of tramadol hydrochloride. Tramadol, the active substance is a pain killer belonging to the class of opioids that acts on the central nervous system. Marol Tablets relieve pain by acting on specific nerve cells of the brain and spinal cord. Marol Tablets are used for the treatment of moderate to severe pain.

2

What you need to know before you take Marol Tablets

Do not take Marol Tablets:

- If you are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- In acute poisoning with alcohol, sleeping pills, pain relievers, or other psychotropic medicines (medicines that affect mood and emotions).
- If you are also taking MAO-inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Marol Tablets (see “Other medicines and Marol Tablets”).
- If you are epileptic and your fits are not adequately controlled by treatment.
- As a substitute in drug withdrawal.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Marol Tablets if:

- You think that you are addicted to other pain relievers (opioids);
- You suffer from consciousness disorders (if you feel that you are going to faint);
- You are in a state of shock (cold sweat may be a sign of this);
- You suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- You suffer from a liver or kidney disease;
- You have difficulty in breathing;
- You have a tendency towards epilepsy or fits because the risk of a fit may increase.

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg). Please note that Marol Tablets may lead to physical and psychological addiction. When Marol Tablets are taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with Marol Tablets should only be carried out for short periods and under strict medical supervision.

Please also inform your doctor if one of these problems occurs during treatment with Marol Tablets or if they applied in the past.

Other medicines and Marol Tablets:

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. Marol Tablets should not be taken together with MAO inhibitors (certain medicines for the treatment of depression). The pain relieving effect of Marol Tablets may be reduced and the length of time it acts may be shortened, if you also take medicines containing:

- Carbamazepine (for epileptic fits)
- Buprenorphine, nalbuphine, or pentazocine (pain killers)
- Ondansetron (prevents nausea)

Your doctor will tell you whether you should take Marol Tablets and what dose.

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 Marol Tablets at the same time. Your doctor will tell you whether Marol Tablets are suitable for you.
- if you are taking certain antidepressants. Marol Tablets may interact with these medicines and you may experience symptoms such as 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.

- if you take coumarin anticoagulants (medicines for blood thinning), such as warfarin, together with Marol Tablets. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- if you take tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Marol Tablets. You may feel drowsier or feel that you might faint. If this happens tell your doctor.

Taking Marol Tablets with food and alcohol:

Do not drink alcohol during treatment with Marol Tablets as its effect may be intensified. Food does not influence the effect of Marol Tablets.

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.

There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Marol Tablets if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

Generally, the use of Marol Tablets is not recommended during breast-feeding. Small amounts of tramadol are excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. Please ask your doctor for advice.

Driving and using machines:

Marol Tablets can cause drowsiness, dizziness, and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3

How to take Marol Tablets

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken.

Unless otherwise prescribed by your doctor, the recommended dose is:

Adults and adolescents from the age of 12 years:

One Marol 100mg Tablet twice daily (equivalent to 200 mg tramadol hydrochloride per day), preferably in the morning and evening.

One Marol 150mg Tablet twice daily (equivalent to 300 mg tramadol hydrochloride per day), preferably in the morning and evening.

One Marol 200mg Tablet twice daily (equivalent to 400 mg tramadol hydrochloride per day), preferably in the morning and evening.

Your doctor may prescribe a different, more appropriate dosage strength of Marol Tablets if necessary. Do not take more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

Use in children

Marol Tablets are not suitable for children below the age of 12 years.

Elderly patients

In elderly patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.

Severe liver or kidney disease (insufficiency)/dialysis patients

Patients with severe liver and/or kidney insufficiency should not take Marol Tablets. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when you should take Marol Tablets:

Marol Tablets are for oral use. Always swallow Marol Tablets whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the tablets on an empty stomach or with meals.

How long should you take Marol Tablets:

You should not take Marol Tablets for longer than necessary. If you need to be treated for a longer period, your doctor will check at regular short intervals (if necessary with breaks in treatment) whether you should continue to take Marol Tablets and at what dose.

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

Pharma Code
Positional

If you take more Marol Tablets than you should:

If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.

After taking very high doses, pin-point pupils, vomiting, fall in blood pressure, fast heart beat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing may occur. In such cases a doctor should be called immediately!

If you forget to take Marol Tablets

If you forgot to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking tablets as before.

If you stop taking Marol Tablets

If you interrupt or finish treatment with Marol Tablets too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

Generally there will be no after – effects when treatment with Marol Tablets is stopped. However, on rare occasions, people who have been taking Marol Tablets for some time may feel unwell if they abruptly stop taking them. They may feel agitated, anxious, nervous or shaky. They may be confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, hallucinations, delusions, paranoia or feeling a loss of identity. They may experience unusual perceptions such as itching, tingling and numbness, and “ringing” in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of their own personality (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely. If you experience any of these complaints after stopping Marol Tablets, please consult your doctor.

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. Usually the frequency of side effects is classified as follows:

- very common (may affect more than 1 in 10 people),
- common (may affect up to 1 in 10 people),
- uncommon (may affect up to 1 in 100 people),
- rare (may affect up to 1 in 1,000 people)
- very rare (may affect up to 1 user in 10,000)
- not known (frequency cannot be estimated from the available data).

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.

The most common side effects during treatment with Marol Tablets are nausea and dizziness, which occur in more than in 1 in 10 patients.

Heart and blood circulation disorders

Uncommon: effects on the heart and blood circulation (pounding of the heart, fast heart beat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain.

rare: slow heart beat, increase in blood pressure.

Metabolism and nutrition disorders

Not known: decrease in blood sugar level

Nervous system disorders

Very common: dizziness.

Common: headaches, drowsiness.

Rare: changes in appetite, abnormal sensations (e.g. itching, tingling, numbness), trembling, slow breathing, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope).

If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.

Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.

Not known: speech disorders

Psychiatric disorders

Rare: hallucinations, confusion, sleep disorders, anxiety and nightmares.

Psychological complaints may appear after treatment with Marol Tablets. Their intensity and nature may vary (according to the patient's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (slowing down but sometimes an increase in activity) and being less aware and less able to make decisions, which may lead to errors in judgment.

Dependence may occur.

Eye disorders

Rare: blurred vision

Not known: extreme pupil dilation (mydriasis).

Respiratory disorders

Rare: shortness of breath (dyspnoea).

Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.

Stomach and bowel disorders

Very common: feeling sick.

Common: being sick, constipation, dry mouth.

Uncommon: urge to vomit (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea.

Skin disorders

Common: sweating.

Uncommon: skin reactions (e.g. itching, rash).

Muscle disorders

Rare: weak muscles.

Liver and biliary disorders

Very rare: increase in liver enzyme values.

Urinary disorders

Rare: passing urine with difficulty or pain, passing less urine than normal

General disorders

Common: fatigue.

Immune system disorders

Rare: allergic reactions (e.g. difficulty breathing, wheezing, swelling of the skin) and shock (sudden circulatory failure) come in very rare cases.

If Marol Tablets are taken over a long period of time dependence may occur, although the risk is very low. When treatment is stopped abruptly signs of withdrawal may appear (see “If you stop taking Marol Tablets”).

Reporting of side effects

If you get any of the 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Marol Tablets

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 blister and / or bottle and 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 to protect the environment.

6 Contents of the pack and other information

What Marol Tablets contain:

The active substance is: tramadol hydrochloride

- 1 Marol 100 mg tablet contains 100 mg tramadol hydrochloride
- 1 Marol 150 mg tablet contains 150 mg tramadol hydrochloride
- 1 Marol 200 mg tablet contains 200 mg tramadol hydrochloride

The other ingredients are: calcium hydrogen phosphate dihydrate (E341), hydroxypropyl cellulose (E463), colloidal anhydrous silica (E551), and magnesium stearate (E470b).

What Marol Tablets look like and contents of the pack

Marol 100mg Tablets are off white, round biconvex tablets

Marol 150mg Tablets are off white, capsule shaped tablets

Marol 200mg Tablets are off white, capsule shaped tablets

All the strengths are available in either clear or opaque coloured blister packs and pots of 10, 20, 30, 50, 60, 90, 100, 120, and 180 tablets but not all pack sizes may be marketed.

Marketing Authorisation Holder:

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Manufacturers:

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This leaflet was last revised in October 2017.