

## Package Leaflet: Information for the User

### Mabron 100 mg, 150 mg and 200 mg Prolonged release tablets

Tramadol Hydrochloride

**This medicine contains tramadol hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**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 Mabron Tablets are and what they are used for
2. What you need to know before you take Mabron Tablets
3. How to take Mabron Tablets
4. Possible side effects
5. How to store Mabron Tablets
6. Contents of the pack and other information

#### **1. What Mabron Tablets are and what they are used for**

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

This medicine has been prescribed for you for the treatment of moderate to severe pain. It contains tramadol hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'.

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

**Mabron Prolonged-release tablets are referred to as Mabron Tablets below.**

#### **2. What you need to know before you take Mabron Tablets**

##### **Do not take Mabron 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 Mabron Tablets (see “Other medicines and Mabron 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 Mabron Tablets if:**

- You are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- You feel you need to take more Mabron Tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever
- You suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see ‘Other medicines and Mabron Tablets’)
- 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.

**Tolerance, dependence, and addiction**

This medicine contains tramadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Mabron Tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

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 Marol Tablets 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.

If you notice any of the following signs whilst taking Marol Tablets, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor.
- You need to take more than the recommended dose.
- You are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’.

- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

**If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Marol Tablets).**

#### Sleep-related breathing disorders

Tramadol 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.

The risk of experiencing central sleep apnea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnea.

Epileptic fits have been reported in patients taking Tramadol at the recommended dose level. The risk may be higher when doses of Tramadol exceed the recommended upper daily dose limit (400mg).

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, contact your doctor, who will decide if you need to take hormone supplement.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Tramadol hydrochloride is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

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

### **Other medicines and Mabron Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tramadol should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of Mabron Tablets may be reduced and the length of time it acts may be shortened, if you take medicines which contain carbamazepine (for epileptic fits) or ondansetron (prevents nausea).

Your doctor will tell you whether you should take Mabron Tablets, and what dose. The risk of side effects increases:

- if you are taking other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Mabron Tablets. You may feel drowsier or feel that you might faint. If this happens tell your doctor
- concomitant use of Mabron Tablets and tranquillizers or sleeping pills (e.g. benzodiazepines), 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 prescribes Mabron Tablets together with sedating medicines the dose and the duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating medicines you are taking, 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 medicines which may cause convulsions (fits), such as certain antidepressants (e.g. venlafaxine) or antipsychotics. The risk of having a fit may increase if you take Mabron Tablets at the same time as those medicines. Your doctor will tell you whether Mabron Tablets are suitable for you
- if you are taking certain antidepressants Mabron Tablets may interact with these medicines and you may experience serotonin syndrome (see section 4 ‘Possible side effects’)
- if you take coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- if you are taking Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

### **Children and adolescents**

#### Use in children with breathing problems

Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

### **Taking Mabron Tablets with food, drink and alcohol**

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

### **Pregnancy, breast-feeding and fertility**

Do not take Mabron Tablets if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you take Mabron Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Mabron Tablets while you are breast-feeding as tramadol hydrochloride passes into breast milk and will affect your baby.

Based on human experience tramadol is suggested not to influence female or male fertility.

### **Driving and using machines**

Mabron 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:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - 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 Mabron Tablets**

Always take 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.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Marol Tablets, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

#### Adults and adolescents from the age of 12 years:

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

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

One Mabron 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 Mabron 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

Mabron 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 Mabron 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 Mabron Tablets:

Mabron Tablets are for oral use.

Always swallow Mabron 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.

#### **If you take more Mabron 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.

If you (or someone else) swallow a lot of Mabron Tablets at the same time you should go to hospital or call a doctor straight away. Signs of an overdose include very small pupils, being sick, a fall in blood pressure, a fast heartbeat, collapse, unconsciousness, fits and breathing difficulty or shallow breathing.

#### **If you forget to take Mabron 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 Mabron Tablets**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you have 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. 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 Mabron Tablets are nausea and dizziness, which occur in more than 1 in 10 people.

##### **Very Common (may affect more than 1 in 10 people)**

- Dizziness
- Feeling sick (nausea).

##### **Common (may affect up to 1 in 10 people)**

- Headache, drowsiness
- Fatigue
- Constipation, dry mouth, being sick (vomiting)
- Sweating (hyperhidrosis).

##### **Uncommon (may affect up to 1 in 100 people)**

- Effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain.
- Urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea
- Skin reactions (e.g. itching, rash).

##### **Rare (may affect up to 1 in 1,000 people)**

- Allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases.
- Slow heartbeat
- Increase in blood pressure
- Abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders
- 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
- Changes in appetite
- Hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- Psychological complaints may appear after treatment with Tramadol. 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 (usually suppression, occasionally increase) and decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgment).
- Blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupils (miosis)
- Slow breathing, shortness of breath (dyspnoea)

- Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- Weak muscles
- Passing urine with difficulty or pain, passing less urine than normal (dysuria).

**Very rare (may affect up to 1 in 10,000 people)**

- Hepatic enzyme increased.

**Not known (frequency cannot be estimated from the available data)**

- Decrease in blood sugar level
- Dependence and addiction (see section “How do I know if I am addicted?”)
- Hiccups
- Serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 ‘What you need to know before you take Mabron Tablets’).

**Drug Withdrawal**

When you stop taking Mabron Tablets, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

**How do I know if I am addicted?**

If you notice any of the following signs whilst taking Mabron Tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

**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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Mabron Tablets**

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

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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 Mabron Tablets contain:**

The active substance is: tramadol hydrochloride

- 1 Mabron 100 mg tablet contains 100 mg tramadol hydrochloride
- 1 Mabron 150 mg tablet contains 150 mg tramadol hydrochloride
- 1 Mabron 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 Mabron Tablets look like and contents of the pack**

Mabron 100mg Tablets are off white, round biconvex tablets

Mabron 150mg Tablets are off white, capsule shaped tablets

Mabron 200mg Tablets are off white, capsule shaped tablets

Mabron 100mg Tablets: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blisters or in plastic tablet containers.

Mabron 150mg Tablets: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blisters or in plastic tablet containers.

Mabron 200mg Tablets: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blisters or in plastic tablet containers.

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 May 2024**