Technical

What you need to know before you take

NA

Profile

What Tramadol capsules are and what they

frequency cannot be estimated from the

may affect up to 1 in 10,000 people):

being sick, diarrhoea, shaking, shivering or sweating.

heartbeat (palpitations), increased blood pressure, feeling or
difficulty sleeping, irritability, agitation, anxiety, feeling your
drug withdrawal symptoms, which include restlessness,
make decisions, which may lead to errors in judgement).

blurred vision, excessive dilation of the pupils (mydriasis),
constriction of the pupil (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):

• liver enzymes increased

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

decrease in blood sugar level

dependency and addiction (see section “How do I know if I
am addicted?”).

Drug Withdrawal

When you stop taking Tramadol capsules, 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 Tramadol
capsules, 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 side effects, talk to your doctor, pharmacist or
nurse. 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 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 Tramadol capsules

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not take Tramadol capsules after the expiry date stated on the
label/carton/bottle. The expiry date refers to the last day of
that month.

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

Contents of the pack and other information

Tramadol capsules contain

• The active substance is tramadol hydrochloride.

• The other ingredients are pregelatinised starch,

microcrystalline cellulose (E460), magnesium stearate

• The capsule shell contains gelatin, iron oxide (E172),

lactose dihydrate (E914), indigo carmine (E111). The printing ink
contains shellac, glaze, iron oxide black (E172) and propylene
glycol.

Tramadol capsules look like and contents of the pack

Tramadol capsules are yellow and green, opaque, hard gelatin
capsules printed “TK” in black.

Pack sizes are 30 and 100.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

Date of revision: April 2020

1 What Tramadol capsules are and what they

are used for

This medicine has been prescribed for you for the relief of
moderate or 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.

12.02.2020

Copyright © Accord Healthcare Ltd 2019

Tramadol capsules are used for

• for pain relief, including moderate or severe pain

• as a substitute in drug withdrawal.

• if you are an epileptic and your fits are not adequately
controlled by treatment.

• as a substitute in drug withdrawal.

• if you are breast-feeding.

Warnings and precautions:

Talk to your doctor or pharmacist before taking

Tramadol capsules if you:

• are allergic to tramadol hydrochloride, or any of the
ingredients of this medicine (listed in section 6).

• in acute poisoning with alcohol, sleeping pills, pain
relievers or other psychoactive 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 Tramadol
(capsules (see “Other medicines and Tramadol capsules”)).

• if you are epileptic and your fits are not adequately
controlled by treatment.

• you have difficulty in breathing;

• suffer from increased pressure in the brain (possibly after
a head injury or brain disease);

• have difficulty in breathing;

• have a tendency towards epilepsy or fits because the risk
of a fit may increase;

• suffer from a liver or kidney disease;

• are or have ever been addicted to opioids, alcohol,
prescription medicines, or illegal drugs.

• have previously suffered from withdrawal symptoms
such as agitation, anxiety, shaking or sweating, when you
have stopped taking alcohol or drugs.

• feel you need to take more Tramadol capsules 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.

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.

Rare

• skin reactions (e.g. itching, rash)

• increase in blood pressure

• abnormal sensations (e.g. pins and needles), 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.

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.

11/02/20
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, shakiness, 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.

Sleep-related breathing disorders

Trazodone capsules contain an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/pause of breathing during sleep) and sleep-related hypoaxemia (low level of oxygen in the blood).

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

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 also inform your doctor if one of these problems occurs during Trazodone treatment or if they applied to you in the past.

Trazodone 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 during sleep) and sleep-related hypoxemia (low level of oxygen in the blood).

Pregnancy, breast feeding and fertility

Do not take Trazodone capsules 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 use Trazodone capsules during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Trazodone capsules while you are breastfeeding as Trazodone 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

Trazodone capsules may make you feel drowsy, dizzy or in rare cases blur your vision. This may be made worse if you drink alcohol or take other medicines such as strong painkillers with tramadol. Make sure you are not affected before you drive 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.

If you have had an initiating treatment for a medical or dental problem and

You may be required to see your prescriber or you may be not sure whether it is safe for you to drive while taking this medicine.

How to take Trazodone capsules

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. Do not take more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

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

• Adults and adolescents from the age of 12 years. One or two Trazodone capsules (equivalent to 50 mg – 100 mg tramadol hydrochloride) Depending on the pain the effect lasts for about 4–8 hours.

Your doctor may prescribe a different, more appropriate dosage of Trazodone if necessary.

Children

Trazodone 50 mg Capsules 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 Trazodone capsules. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Trazodone capsules?

Trazodone capsules are oral use.

Always swallow Trazodone capsules whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty stomach or with meals.

How long should you take Trazodone capsules

Your prescriber should have discussed with you, how long the course of Trazodone capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

You should not take Trazodone capsules 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 Trazodone capsules and at what dose.

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

If you take more Trazodone capsules 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 Trazodone capsules 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, fall in blood pressure, fast heart beat, collapse, unconsciousness, fits and breathing difficulties or shallow breathing.

If you forget to take Trazodone capsules

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

If you stop taking Trazodone capsules

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

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. Very few people may get panic attacks, hallucinations, unusual perceptions such as tinnitus, tingling and numbness, and ‘ringing’ in the ears (tinnitus). Further unusual central nervous system symptoms, such as confusion, delusions, change of perception of the 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 tramadol, please consult your doctor.

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

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.

Very uncommon (may affect more than 1 in 10 people):

• dizziness, feeling sick (nausea)

Common (may affect up to 1 in 10 people):

• headaches, drowsiness, fatigue, constipation, dry mouth, being sick (vomiting), sweating (hyperhidrosis)
How do I know if I am addicted? If you notice any of the following signs whilst taking Tramadol capsules, 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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 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.

How to store Tramadol capsules
Keep out of the sight and reach of children. Do not store above 30°C.

Do not take Tramadol capsules after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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

Contents of the pack and other information
What Tramadol capsules contain
- The active substance is tramadol hydrochloride.
- Other ingredients are pregabaline stearate, microcrystalline cellulose (E460), magnesium stearate, the capsule shell contains gelatin, iron oxide (E172), titanium dioxide (E171), and propylene glycol.

What Tramadol capsules look like and contents of the pack
Tramadol capsules are yellow and green, opaque, hard gelatin capsules printed "TK" in black.

Pack sizes are 30 and 100.

Marketing Authorisation Holder and Manufacturer
Accord Barnstaple, EX32 8NS, UK
Date of revision: April 2020

What is in this leaflet
1. What Tramadol capsules are and what they are used for
2. What you need to know before you take Tramadol capsules
3. How to take Tramadol capsules
4. Possible side effects
5. How to store Tramadol capsules
6. Contents of the pack and other information

What Tramadol capsules are and what they are used for
This medicine has been prescribed for you for the relief 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Tramadol capsules if you:
- are allergic to tramadol hydrochloride, or any of the ingredients of this medicine (listed in section 6).
- are in a state of shock (cold sweat may be a sign of this).
- have previously suffered from withdrawal symptoms in the brain (possibly after a head injury or brain disease).
- have difficulty in breathing; have a tendency towards epilepsy or fits because the risk of a fit may increase.
- suffer from a liver or kidney disease;
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more Tramadol capsules 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 a different pain reliever.

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.