

TRAMAL(R) SR

Sustained Release Tablets

Tramadol hydrochloride

Consumer Medicine Information

Important

The name of your medicine is TRAMAL(R) SR. Before taking TRAMAL(R) SR, please read this leaflet carefully. It is intended to answer questions you may have about TRAMAL(R) SR. It does not contain all the available information. It does not replace talking to your doctor or pharmacist.

You may wish to read this leaflet again, do not throw it away until you have finished using this medicine.

All medicines have risks and benefits. If you have any concerns or want more information about your medicine, ask your doctor or pharmacist.

What is TRAMAL(R) SR used for?

TRAMAL(R) SR is used to relieve moderate to severe pain. It belongs to the group of medicines called analgesics (pain relievers). TRAMAL(R) SR tablets are designed to release the pain reliever gradually over several hours.

Before taking TRAMAL(R) SR for the first time

Tell your doctor

- * if you are allergic to any of the ingredients in TRAMAL(R) SR

(see "What is in TRAMAL(R) SR?" on page 3)

- * if you are known to be sensitive to opioids
- * if you have lung or breathing problems
- * if you are taking any medicines for depression, or mental or psychiatric disorder or to help you sleep
- * if you are taking medication known as SSRI's, tricyclic anti-depressants, quinidine, phenothiazines or anti psychotics
- * if you have had any fits or convulsions, or take medicines for epilepsy
- * if you are taking the medicine carbamazepine (one Brand name is Tegretol)
- * if you have any disorder of the kidney, liver or pancreas, including any related to alcohol intake, for example, cirrhosis of the liver
- * if you have a stomach problem
- * if you have a severe headache or have had a head injury
- * if you have, or have had, any drug or alcohol dependence
- * if you are taking any other medicine, including those you buy from a pharmacy or supermarket
- * if you have galactose intolerance, or lactase deficiency or glucose-galactose malabsorption.

Use in children

TRAMAL(R) SR is not recommended for children under 12 years.

Use in elderly

Patients over 75 years may need a reduced daily dose of TRAMAL(R) SR compared to younger adults.

If you are pregnant or intend to become pregnant:

TRAMAL(R) SR is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using TRAMAL(R) SR during pregnancy.

If you are breast-feeding or plan to breast feed:

TRAMAL is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits using TRAMAL when breast-feeding.

If you are driving or operating machinery

TRAMAL(R) SR may make you drowsy or dizzy. Ask your doctor for advice about whether it is safe for you to drive or operate machinery while taking TRAMAL(R) SR.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with TRAMAL(R) SR. These include:

- * carbamazepine (eg. Tegretol)
- * coumarin derivatives (eg. Warfarin: some Brand names are Coumadin, or Marevan)
- * medicine for irregular or rapid heart beat

- * medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- * some antibiotics.

These medicines may be affected by TRAMAL(R) SR, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Other interactions not listed above may also occur.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking TRAMAL(R) SR.

When should TRAMAL(R) SR not be used?

You should NOT use TRAMAL(R) SR

- * if you have an allergy to any of the ingredients (see page 3 for details)
- * if you have an allergy to any other medicines known as opioid analgesics, eg. morphine or codeine.
- * if you have taken large amounts of alcohol or other substances which can affect your level of consciousness
- * if you are taking medicine for depression containing a "monoamine oxidase inhibitor" also known as MAOI, or have taken any within the past two weeks. Examples of MAOI-containing medicines are Nardil, Parnate.
- * if you are having treatment for withdrawal from narcotics
- * if the packaging is torn or shows signs of tampering
- * if any tablets look damaged or discoloured
- * if it is after the expiry date which is printed on the carton box.

How should TRAMAL(R) SR be used?

TRAMAL(R) SR tablets should be swallowed whole with water. They maybe taken, before, with, or after food.

They must NOT be chewed, crushed or dissolved. This will release all the analgesic quite quickly. Side-effects may then occur.

The recommended dosage of TRAMAL(R) SR is either:

- * two TRAMAL(R) SR 50 tablets twice a day (morning and evening)

OR

- * one or two TRAMAL(R) SR 100 mg tablet(s) twice a day (morning and evening)

OR

- * one TRAMAL(R) SR 150 mg or 200 mg tablet twice a day (morning and evening).

As all patients respond to treatment differently, your doctor may start you on a lower dose.

Do not take more than eight of the 50 mg tablets per day.

Do not take more than four of the 100 mg tablets per day

Do not take more than two of the 150 mg or of the 200 mg tablets per day.

What to do if you have missed your dose

If you forget to take one dose, take the dose when you remember. The following dose should be taken after twelve hours, or as prescribed by your doctor.

For how long should you take TRAMAL(R) SR?

This is very individual: it depends for example how severe your pain is, how you respond to TRAMAL(R) SR, and the cause of your pain. Ask your doctor for advice on how long you need to take TRAMAL(R) SR tablets.

TRAMAL (capsules and injection) are also available and they provide moderate to severe pain relief.

As with all medicine,

- * take only as your doctor has told you.
- * if you feel that you do not need as much TRAMAL(R) SR as your doctor has prescribed for you, talk to your doctor.
- * tell your doctor if your pain is not helped or gets worse. Do not take increased amounts or extra doses of TRAMAL(R) SR unless your doctor advises you to.

What are the side effects of TRAMAL(R) SR?

All medicines can cause unwanted effects, and some side-effects have been reported with TRAMAL(R) SR. Side-effects reported with TRAMAL(R) SR are usually minor and temporary, but some may be serious.

The most common side-effects of TRAMAL(R) SR are:

- * dizziness
- * sedation, fatigue
- * headache
- * constipation
- * nausea, vomiting
- * sweating
- * dry mouth.

The following side-effects are less common:

- * indigestion
- * changes in appetite
- * skin reactions
- * sudden onset of low blood pressure, collapse
- * muscle weakness
- * tremor
- * seizures
- * respiratory depression
- * improvement of mood
- * confusion
- * sleep disturbance

- * blurred vision
- * difficulty in passing urine
- * Serotonin Syndrome: signs of this vary and are not specific; they may include fever, sweating, confusion, agitation, diarrhoea, muscle twitching, difficulty with walking and balance. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.

This is not a complete listing. Occasionally, other side-effects may be experienced. Tell your doctor immediately if you experience any of the following side-effects, as urgent medical treatment may be required:

- * skin rash (red spots or patches), itching hives, skin lumps
- * swelling or puffiness of the eyelids, face or lips
- * chest tightness, wheezing or pain in the chest
- * heart palpitations, faintness or collapse
- * hallucinations
- * convulsions

If you experience any side-effects that have not been mentioned here, consult your doctor or pharmacist as soon as possible.

You should remember that all medicines carry some risks. It is possible that some risks might not yet have been detected despite many years of experience with the medicine.

Can TRAMAL(R) SR be addictive?

When used as prescribed by your doctor, addiction to TRAMAL(R) SR is very unlikely.

If you are taking TRAMAL(R) SR for a prolonged period of time, your body may become used to the medicine and mild withdrawal symptoms may occur if you suddenly stop taking the medicine.

It is important therefore to take TRAMAL(R) SR only as directed by your doctor.

What to do in the case of overdose

In the event of overdose, you should contact your nearest Poisons Information Centre (tel: 131 126), doctor or hospital emergency department immediately.

Overdosage with TRAMAL(R) SR will result in decrease in breathing and fits or convulsions.

How should TRAMAL(R) SR be stored?

- * Keep TRAMAL(R) SR in a safe place, where children cannot reach it.
- * Store in a cool, dry place, below 30 degrees C.
- * Keep away from direct sunlight.
- * Do not use TRAMAL(R) SR after the use-by-date printed on the label of the pack.

What is in TRAMAL(R) SR

The active medicine in TRAMAL(R) SR is called tramadol hydrochloride.

It is specially made up into tablets that allow the body to absorb the tramadol over a long period, so that dosing need be only twice a day.

TRAMAL(R) SR is available as four distinct strengths of tablet. Each strength of tablet contains a different amount of the active ingredient, tramadol hydrochloride.

TRAMAL(R) SR Tablet 50 mg

Pale yellow, round. One side imprinted with GRUNENTHAL logo. Other side engraved with "T0"

Available in packs of 20 or 60 tablets.

TRAMAL(R) SR Tablet 100 mg

White, round. One side imprinted with GRUNENTHAL logo. Other side engraved with "T1" Available in packs of 20 or 60 tablets

TRAMAL(R) SR Tablet 150 mg

Pale orange. One side imprinted with GRUNENTHAL logo. Other side engraved with "T2" Available in packs of 20 or 60 tablets

TRAMAL(R) SR Tablet 200 mg

Deep orange to brown. One side imprinted with GRUNENTHAL logo. Other side engraved with "T3" Available in packs of 20 or 60 tablets

TRAMAL(R) SR tablets also contain the inactive ingredients:

- * hypromellose
- * silica-colloidal anhydrous
- * microcrystalline cellulose
- * magnesium stearate
- * lactose
- * macrogol 6000
- * propylene glycol
- * talc
- * titanium dioxide
- * quinoline yellow aluminium lake CI47005 (150 and 200 mg tablets)
- * iron oxide red CI77491 (150 and 200 mg tablets)
- * iron oxide yellow CI77492 (50 mg and 200 mg tablets only)
- * iron oxide black CI77499 (200 mg tablets).

TRAMAL(R) SR tablets are sealed in a blister foil pack.

Other information you need to know about TRAMAL(R) SR

- * TRAMAL(R) SR is available only on a doctor's prescription.
- * Do not give your medicine to anyone else, even if they have

similar symptoms to you. Your medicine is for your use only, it may harm other people.

- * This leaflet does not contain all the available information about TRAMAL(R) SR. Contact your doctor or pharmacist if you have any questions about the information in this leaflet or other questions about your medicine.

**TRAMAL(R) SR is made by
Grunenthal GmbH in Germany
and supplied in Australia by:**

CSL Limited
ABN 99 051 588 348
45 Poplar Road
Parkville 3052
Victoria Australia

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August 2000

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AUST R 121845: Tablets 50 mg
AUST R 75947: Tablets 100mg
AUST R 75948: Tablets 150mg
AUST R:75949: Tablets 200mg

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