

Tramadol STADA 100 Suppositories

Tramadol hydrochloride 100mg

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Product description

Manufacturer

Marketing Authorisation Holder

Date of revision

What Tramadol STADA 100

Suppositories is used for

Treatment of moderate to severe pain

How Tramadol STADA 100

Suppositories works

Tramadol STADA 100 Suppositories is a painkiller belonging to the class of the opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

Before you use Tramadol STADA 100

Suppositories

When you must not take it

- if you are allergic to the active substance tramadol hydrochloride or to any of the other ingredients of Tramadol STADA 100 Suppositories
- in acute intoxication with alcohol, analgesics, sedatives or other psychotropic drugs
- if you are also taking monoamine oxidase (MAO) inhibitors
- if you have taken MAO inhibitors within two weeks of when you will start taking Tramadol STADA 100 Suppositories

Before you start to take it

You should tell your doctor if

- The pressure inside your skull is higher than normal.

- You have difficulty in breathing
- You suffer from consciousness disorders
- You suffer from a liver or kidney disease
- You think that you are addicted to other pain relievers

Taking other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

DO NOT take Tramadol STADA 100 Suppositories with monoamine oxidase inhibitors (MAOI), or 2 weeks before and after taking these medicines. MAOs are medicines used for depression.

The effect of Tramadol STADA 100 Suppositories may be greater if you are:

- also taking other medicines which act on your central nervous system
- drinking alcohol

You may feel drowsier or feel that you might faint. If this happens tell your doctor.

You should take care if you are also taking:

- Medicines which may cause convulsions, for instance medicines for the treatment of psychological diseases. The risk having a fit may increase if you take Tramadol STADA 100 Suppositories at the same time.
- Selective serotonin re-uptake inhibitors used to treat depression.

How to take Tramadol STADA 100 Suppositories

How much to take

Always take Tramadol STADA 100 Suppositories exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Unless otherwise prescribed, the following dosage guidelines apply. The recommended dosage are guidelines only. In principle, the lowest effective analgesic dose should be chosen. In the treatment of chronic pain, strict time-tabling of doses is preferred.

Single dose for adults and juveniles over the age of 14: 1 Tramadol STADA Suppository (equivalent to 100 mg tramadol hydrochloride). Daily doses of 4 suppositories (equivalent to 400 mg of tramadol hydrochloride) will not usually have to be exceeded for adequate pain control. However, significantly higher doses may be needed for the management of cancer pain and severe pain after surgery.

On account of dosage strength, suppositories are not recommended for children below the age of 14 years. Geriatric patients 65 years of age under with normal renal and hepatic function do not usually need a dose adjustment. However, in patient more than 75 years of age, elimination may be prolonged, perhaps requiring an individualized increase in dosing intervals and daily dosage not exceeding 300 mg. Tramadol STADA 100 Suppositories should not be administered to patients with severe hepatic and or renal insufficiency. Increasing the dosing interval should be considered in less severe cases.

When to take it

The suppositories should be introduced deep into the anus. If possible after defaecation. For smoother insertion, warm suppository in your hand or briefly dip into hot water.

How long to take it

Your doctor will tell you for how long you should take Tramadol STADA 100 Suppositories. Tramadol should not in any circumstances be used longer than therapeutically absolutely necessary.

If you forget to take it

If you forget to take a dose of Tramadol STADA 100 Suppositories just take the next dose at the usual time. DO NOT take a double dose to make up for the missed one.

If you take too much (overdose)

After taking very high doses, constricted or dilated pupils, fast hear beat, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and

difficulty in breathing up to cessation of breathing may occur. Gastric lavage may be useful in oral intoxication. In such cases, contact your doctor or go to your nearest emergency department immediately!

Your doctor will treat the symptoms of Tramadol STADA overdose.

While you are using Tramadol STADA 100 Suppositories

Things you must do

Always take Tramadol STADA 100 Suppositories exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Things you must not do

- Do not drink alcohol during treatment with Tramadol STADA 100 Suppositories as its effect may be intensified.
- You should not take Tramadol STADA 100 Suppositories long-term during pregnancy.
- Don't take more than a single dose of Tramadol STADA 100 Suppositories while breast-feeding your baby.
- Do not use Tramadol STADA 100 Suppositories after the expiry date printed on the container.

Things to be careful of

Even when Tramadol STADA 100 Suppositories is used approximately, the capacity to drive in traffic or operate machinery may be abolished.

Pregnancy

Adequate systematic studies on usage of tramadol during pregnancy have not been carried out. Chronic treatment should be avoided throughout pregnancy.

Breast-feeding

Very small amounts of Tramadol STADA 100 Suppositories may pass

through your breast-milk to your infant. With a single dose of tramadol, interruption of breast-feeding is usually unnecessary.

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Side effects

Very common: nausea, Dizziness

Common: Dry mouth, Headache, Sweating, Drowsiness, fatigue

Uncommon:

- Gastrointestinal irritation (a feeling of pressure in the stomach, bloating)
- Vomiting
- Constipation
- Cardiovascular regulation including feeling your heartbeat (palpitations), rapid heartbeat (tachycardia), feeling dizzy or faint on standing (postural hypotension), when there is not enough circulation of blood because the heart does not work properly (circulatory collapse)
- Skin reactions including itching (pruritus) and rash.

Rare:

- Changes in appetite
- Changes in mood – usually high spirits (elation), occasionally an unpleasant mood (dysphoria)
- Changes in activity (usually less active, occasionally more active)
- Changes in your ability to think and feel things clearly such as: making

decisions and perception disorders

- weak muscles
- passing urine with difficulty or pain, passing less urine than normal
- allergic reaction
- extending to shock

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

After using Tramadol STADA 100 Suppositories

Storage

Keep out of the reach and sight of children.

Do not store above 25°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like?

Tramadol STADA 100 Suppositories appears as white, homogenous suppositories. Tramadol STADA 100 Suppositories is available in the pack of 30 suppositories.

Ingredients

The active substance is tramadol hydrochloride.

The other ingredient is hard fat.

MAL06011688ACS

Manufacturer

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Marketing Authorisation Holder

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Selangor.

Date of revision

25 Sep 2012

Tramadol STADA 100 Suppositories

Tramadol hydrochloride 100mg

Apakah yang ada pada risalah ini

Apakah kegunaan Tramadol STADA 100 Suppositories

Bagaimana Tramadol STADA 100 Suppositories berfungsi

Sebelum mengambil Tramadol STADA 100 Suppositories

Cara menggunakan Tramadol STADA 100 Suppositories

Semasa menggunakan Tramadol STADA 100 Suppositories

Kesan-kesan sampingan

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Tramadol STADA 100 Suppositories

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Pemegang Autorisasi Pemasaran

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Apakah kegunaan Tramadol STADA 100 Suppositories

Rawatan untuk kesakitan yang sederhana dan kesakitan yang teruk.

Bagaimana Tramadol STADA 100 Suppositories berfungsi

Tramadol STADA 100 Suppositories ialah ubat pelali sakit yang tergolong dalam kelas opioid yang bertindak pada sistem saraf pusat. Ia melegakan kesakitan dengan bertindak ke atas sel saraf tertentu pada saraf tunjang dan otak.

Sebelum mengambil Tramadol STADA 100 Suppositories

Bila tidak boleh mengambil

- jika anda alergik terhadap bahan aktif tramadol hydrochloride atau mana-mana ramuan Tramadol STADA 100 Suppositories yang lain
- jika anda dalam intoksikasi akut dengan alkohol, analgesik, sedatif atau ubat psikotropik yang lain.
- jika anda juga mengambil inhibitor monoamine oxidase (MAO)
- jika anda telah mengambil inhibitor MAO dalam tempoh dua minggu apabila anda akan mula mengambil Tramadol STADA 100 Suppositories

Sebelum anda mula mengambil

Anda harus memberitahu doktor jika

- tekanan dalam tengkorak anda lebih

tinggi daripada biasa anda mengalami kesukaran untuk bernafas

- anda mengalami gangguan kesedaran
- anda menderitai penyakit hati atau ginjal
- anda rasa bahawa anda ketagihan ubat penahan sakit yang lain

Jika mengambil ubat-ubat lain

Sila beritahu doktor atau ahli farmasi jika anda menggunakan atau baru-baru ini telah menggunakan sebarang ubat lain, termasuk ubat yang anda peroleh tanpa preskripsi.

JANGAN ambil Tramadol STADA 100 Suppositories dengan inhibitor monoamine oxidase (MAOI), atau 2 minggu sebelum dan selepas mengambil ubat-ubat ini. MAO ialah ubat yang digunakan untuk kemurungan.

Kesan Tramadol STADA 100 Suppositories adalah lebih tinggi jika anda:

- juga mengambil ubat lain yang bertindak pada sistem saraf pusat
- minum alkohol

Anda mungkin berasa mengantuk atau berasa anda mungkin pengan. Jika ini berlaku, maklumkan doktor.

Anda perlu berhati-hati jika anda juga mengambil:

- ubat yang boleh menyebabkan konvulsi, misalnya ubat untuk rawatan penyakit psikologi. Risiko mengalami sawan akan meningkat jika anda mengambil Tramadol STADA 100 Suppositories pada masa yang sama.
- inhibitor re-uptake serotonin terpilih yang digunakan untuk merawat kemurungan.

Cara menggunakan Tramadol STADA 100 Suppositories

Berapa banyak harus diambil

Sentiasa mengambil Tramadol STADA 100 Suppositories persis sebagaimana yang diberitahu doktor. Anda harus semak dengan doktor atau ahli farmasi jika anda tidak pasti. Melainkan jika ditetapkan selainnya, garis panduan dos berikut dikenakan. Dos yang dicadangkan adalah

garis panduan sahaja. Pada prinsipnya, dos terendah analgesic yang berkesan harus dipilih. Dalam rawatan sakit kronik, jadual waktu dos yang ketat diperlukan. Dos tunggal untuk orang dewasa dan remaja yang berumur 14 tahun ke atas: 1 Tramadol STADA Suppository (bersamaan dengan 100 mg tramadol hydrochloride). Dos harian yang 4 suppositories (bersamaan dengan 400 mg tramadol hydrochloride) biasanya tidak akan dilebihi untuk mendapatkan kawalan kesakitan yang mencukupi.

Walaubagaimanapun, dos yang lebih tinggi mungkin diperlukan bagi pengurusan kesakitan kanser dan kesakitan teruk selepas pembedahan. Pada akaun kekuatan dos, suppositories tidak disyorkan untuk kanak-kanak di bawah umur 14 tahun.

Pesakit geriatrik berumur 65 tahun dengan fungsi ginjal dan hati normal biasanya tidak memerlukan pelarasan dos.

Walaubagaimanapun, dalam pesakit berumur lebih daripada 75 tahun, eliminasi mungkin berpanjangan, mungkin memerlukan peningkatan dalam selang dos berdasarkan individu dan dos harian tidak melebihi 300 mg. Tramadol STADA 100 Suppositories tidak boleh diberikan kepada pesakit dengan kemerosotan hati dan atau ginjal yang teruk. Peningkatan selang dos perlu dipertimbangkan dalam kes-kes yang kurang teruk.

Bila perlu diambil

Tramadol STADA 100 Suppositories perlu dimasukkan ke dalam dubur dengan mendalam. Jika mungkin, selepas defaecation. Untuk kemasukan lancar, panaskan supositori di tangan anda atau secara ringkas, celup ke dalam air panas.

Berapa lama perlu diambil

Doktor anda akan memberitahu anda berapa lama anda harus mengambil Tramadol STADA 100 Suppositories. Tramadol tidak seharusnya digunakan lebih lama daripada terapeutik yang benar-benar perlu dalam apa-apa keadaan.

Jika terlupa mengambil

Jika anda terlupa mengambil sesuatu dos Tramadol STADA 100 Suppositories, ambil saja dos yang seterusnya pada masa yang biasa. JANGAN ambil dos berganda untuk mengganti dos yang terlepas.

Jika mengambil berlebihan (terlebih dos)

Selepas mengambil dos yang sangat tinggi, anak mata mengecil atau membesar, denyutan jantung mencepat, kesedaran terganggu sehingga ke tahap koma (ketaksedaran yang mendalam), sawan epileptik, dan kesukaran bernafas sehingga terhentinya pernafasan mungkin berlaku. Lavaj gastrik mungkin berkesan dalam oral intoksikasi. Dalam kes sedemikian, hubungi doktor atau pergi ke bahagian kecemasan yang terdekat dengan segera!

Ingat bawa pek dan sebarang baki kapsul bersama dengan anda.

Doktor akan merawat simptom dos berlebihan Tramadol STADA.

Semasa menggunakan Tramadol STADA 100 Suppositories

Perkara yang perlu dilakukan

Sentiasa menagambil Tramadol STADA 100 Suppositories persis sebagaimana yang diberitahu oleh doktor. Anda harus semak dengan doktor atau ahli farmasi jika anda tidak pasti.

Perkara yang tidak boleh dilakukan

- Jangan minum alkohol semasa rawatan dengan Tramadol STADA 100 Suppositories kerana kesannya boleh dipertingkatkan.
- Anda tidak harus mengambil Tramadol STADA 100 Suppositories jangka panjang semasa mengandung.
- Jangan ambil lebih daripada satu dos tunggal Tramadol STADA 100 Suppositories semasa menyusui bayi.
- Jangan guna Tramadol STADA 100 Suppositories selepas tarikh luput yang dinyatakan pada bekas.

Perkara yang perlu diberi perhatian

Tarikh kemaskini

25 Sep 2012

Walaupun jumlah anggaran sahaja Tramadol STADA 100 Suppositories yang digunakan, keupayaan untuk memandu di jalan raya atau mengendalikan jentera boleh terjejas.

Kehamilan

Terdapat sedikit maklumat mengenai keselamatan Tramadol STADA semasa kehamilan. Terapi kronik perlu dielakkan semasa kehamilan.

Menyusu

Jumlah Tramadol STADA 100 Suppositories yang sangat sedikit akan melalui susu ibu sampai kepada bayi. Anda boleh terus menyusui jika anda hanya mengambil dos tunggal Tramadol STADA 100 Suppositories.

Kesan-kesan sampingan

Sangat biasa: Melayu, pening

Biasa: Mulut kering, sakit kepala, berpeluh, mengantuk, keletihan

Tidak biasa:

- Kerengsaan gastrointestinal (berasa tekanan dalam perut, kembung)
- Muntah
- Sembelit
- Pengawalan kardiovaskular termasuk berasa denyutan jantung (berdebar), denyutan jantung yang cepat (tacikardia), berasa pening atau pengsan semasa berdiri (hipertensi postural), apabila peredaran darah tidak cukup kerana jantung tidak berfungsi dengan betul (peredaran runtuh)
- Reaksi kulit termasuk gatal (pruritus) dan ruam.

Jarang:

- Perubahan selera makan
- Perubahan dalam mood – biasanya bersemangat tinggi (kegembiraan), kadang-kadang mood tidak menyenangkan (disforia)
- Perubahan dalam aktiviti (biasanya kurang aktif, kadang-kadang lebih aktif)
- Perubahan dalam kebolehan untuk berfikir dan merasai perkara dengan

jelas seperti: membuat keputusan dan gangguan persepsi

- Otot lemah
- Membuang air kecil dengan kesukaran atau sakit, membuang air kecil kurang daripada biasa
- Reaksi alergik
- Diperluas kepada kejutan

Jika mana-mana kesan sampingan ini menjadi serius, atau jika anda perhatikan mana-mana kesan sampingan yang tidak disenaraikan dalam risalah ini, sila maklumkan doktor atau ahli farmasi.

Cara penyimpanan dan pelupusan Tramadol STADA 100 Suppositories

Penyimpanan

Jauhkan daripada kanak-kanak.

Jangan simpan melebihi 25°C.

Pelupusan

Ubat tidak harus dilupuskan melalui sisa air atau sisa rumah. Tanya ahli farmasi bagaimana melupuskan ubat yang tidak lagi diperlukan. Langkah ini akan membantu untuk melindungi alam sekitar.

Maklumat lanjut

Rupa dan warna produk

Tramadol STADA 100 Suppositories muncul sebagai larutan putih, suppositories homogenus. Tramadol STADA 100 Suppositories boleh didapati dalam pek sebanyak 30 suppositories. Kapsul Tramadol 50 STADA dipakej dalam blister aluminium/PVC. Tramadol 50 STADA tersedia dalam pek 50 kapsul.

Bahan-bahan kandungan

Bahan aktif ialah tramadol hydrochloride. Ramuan lain ialah hard fat.

Nombor MAL: MAL06011688ACS

Pengilang

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Pemegang Autorisasi Pemasaran

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