

ACUGESIC CAPSULE

Tramadol hydrochloride (50mg)

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What ACUGESIC capsule is used for

ACUGESIC capsule is a painkiller used for treatment of severe acute and chronic pain.

ACUGESIC capsule is a medicine for relief of pain, eg. in wound pain, fractures, severe nerve pain, tumor pain, heart attack. It should not be used for minor pain. The effect sets in quickly and lasts for some hours.

How ACUGESIC capsule works

ACUGESIC capsule contains active substance called Tramadol. Tramadol 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 ACUGESIC capsule

- When you must not use it

Do not use ACUGESIC capsule if you have or have had any of the following condition:

- You are less than 12 years old.
- You have slow or shallow breathing, or other breathing problems.
- You are pregnant.
- You are breastfeeding.
- You have recently taken large amounts of alcohol, hypnotics (sleeping pills), analgesics (painkillers) or other medicines that act on the brain and spinal cord.
- You are hypersensitive to, or have had an allergic reaction to tramadol, other opioids or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash itching or hives on the skin; fainting or hay fever like symptoms.

If you think you are having an allergic reaction, stop taking the medicine and contact your doctor immediately or go to the nearest hospital.

- Before you start to use it

You must tell you doctor if:

- Any disease of the kidney and liver
- If you suffered head injury or raised pressure in the skull
- Are in shock

- If you are suffering from myasthenia gravis (a disease of the muscles causing drooping eyelids, double vision, difficulty in

speaking and swallowing, and, sometimes, muscle weakness in the arms or legs).

- You have or have had any problem with drug or alcohol dependence.
- You are pregnant or intend to become pregnant. ACUGESIC capsule is not recommended for use during pregnancy.
- You are breast-feeding or plan to breast-feed.

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

- Taking other medicines

Taking Acugesic with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

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 ACUGESIC capsule. These include:

- Central nervous system (eg. tranquilizers, hypnotics – medications to help you to sleep)
- Monoamine oxidase inhibitors (MAOIs) (often taken for depression)

These medicines may be affected by ACUGESIC capsule, 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 ACUGESIC capsule.

How to use ACUGESIC capsule

- How much to use

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Single dose for adults and adolescents over 14 years of age:

1 capsule to be taken with a little liquid. This is usually sufficient to relieve the pain. If, however, pain relief is unsatisfactory, capsule can be taken after about 30-60 minutes.

In impaired kidney or liver function it may be necessary to adjust the dose.

Do not take more than eight capsule (400mg) per day.

- When to use it

Take ACUGESIC capsule exactly as directed by your doctor. Do not take more than instructed by your doctor.

You are advised NOT to drink alcohol with this medicine.

The effects of ACUGESIC capsule are not affected by food.

- How long to use it

You should not take ACUGESIC capsule 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 ACUGESIC capsule and at what dose.

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

Continue taking ACUGESIC capsule for as long as your doctor recommends.

Duration of treatment: During long-term treatment with TRAMADOL the possibility of dependence cannot be entirely excluded. Therefore the physician is to decide on the duration of treatment and whether the preparation is to be withdrawn temporarily.

- If you forget to use it

If you forget to take a dose, you can take it as soon as you remember. The next dose should be taken as prescribed by your doctor.

Do not take a double dose to make up for the dose that you missed.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much ACUGESIC capsule.

If you taking too many ACUGESIC capsule (overdose), this may result in restlessness, anxiety, tremor, increased reflexes.

While you using it

- Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ACUGESIC capsule.

If your pain is relieved and you feel that you do not need as much ACUGESIC capsule as your doctor ordered, consult your doctor.

Tell your doctor if your pain gets worse. Do not take extra doses without checking with your doctor.

- Things you must not do

Do not give ACUGESIC capsule to anyone else, even if they have the same condition as you.

Do not use ACUGESIC capsule to treat any other complaints unless your doctor tells you to.

- Things to be careful of

Tramadol is not to be used during breast-feeding. Small amounts of tramadol is excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. If you have taken Acugesic when you are

breastfeeding, seek immediate medical attention if you notice your baby has any changes in their breathing (such as weak, difficult or fast breathing).

Be careful driving or operating machinery until you know how ACUGESIC capsule affects you.

ACUGESIC capsule may make you dizzy.

Serotonin syndrome: Acugesic may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency: Long-term use of Acugesic may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility: Long-term use of Acugesic may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Side effects

Check with your doctor as soon as possible if you have any problems while taking ACUGESIC capsule, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, ACUGESIC capsule can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you.

Common side effects:

- Dizziness
- Fatigue
- Nausea or vomiting
- Sweating
- Dry mouth
- Slowed breathing

If ACUGESIC capsule is taken over a long period of time dependence may occur. When treatment is stopped abruptly signs of withdrawal may appear.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers->Reporting->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of ACUGESIC capsule

- Storage

Keep your capsule in the blister pack until it is time to take them.

If you take ACUGESIC out of the blister pack it will not keep well.

Keep the capsule in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave your medicines on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

ACUGESIC CAPSULE
50MG
Black/green capsule with marking 'DUO 861'

- Ingredients

Active Ingredient:

- Tramadol hydrochloride

Inactive Ingredients:

- Magnesium Stearate
- Lactose

- MAL numbers

ACUGESIC CAPSULE
50MG
MAL19950161AZ

Manufacturer

DUOPHARMA (M) SDN.
BHD.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Product Registration Holder

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