

PACKAGE LEAFLET: INFORMATION FOR THE USER

Baclofen Aguettant 2mg/ml, solution for infusion
{baclofen}

Read all of this leaflet carefully before you start using this medicine because 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 nurse.
- 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 your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Baclofen Aguettant is and what it is used for
2. What you need to know before you use Baclofen Aguettant
3. How to use Baclofen Aguettant
4. Possible side effects
5. How to store Baclofen Aguettant
6. Contents of the pack and other information

1. WHAT BACLOFEN AGUETTANT IS AND WHAT IT IS USED FOR

Baclofen Aguettant belongs to a group of medicines called muscle relaxants. Baclofen Aguettant is administered by injection into the spinal canal directly into the spinal fluid (intrathecal injection) and relieves severe muscle rigidity (spasticity).

Baclofen Aguettant is used to treat severe, long-lasting muscle tension (spasticity) occurring in various illnesses, such as:

- brain or spinal cord injuries or diseases
- multiple sclerosis, which is a progressive brain and spinal cord nerve disease with physical and mental symptoms

Baclofen Aguettant is used in adults and children aged 4 years and above. It is used when other orally taken medicines, including baclofen, have been unsuccessful or caused unacceptable side effects.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BACLOFEN AGUETTANT

Do not use Baclofen Aguettant

- if you are allergic to baclofen or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from epilepsy refractory to therapy.
- by any other route of administration than via the spinal canal.

Warnings and precautions

Talk to your doctor or pharmacist before using Baclofen Aguettant

- if you are having any other injections into the spine
- if you are suffering from any infection
- if you had a head injury within the last year
- if you ever had a crisis caused by a condition called autonomic dysreflexia: a reaction of the nervous system to overstimulation, causing sudden severe high blood pressure (Your doctor will be able to explain this to you.)
- if you have had a stroke
- if you have epilepsy
- if you have a stomach ulcer or any other problem with your digestion
- if you suffer from any mental illness
- if you are being treated for high blood pressure
- if you have Parkinson's disease
- if you suffer from any liver, kidney, heart or breathing difficulties
- if you have diabetes
- if you have difficulties in urinating

If the answer to any of this list of questions is YES, tell your doctor or nurse because Baclofen Aguettant may not be the right medicine for you.

- If you are going to have an operation of any kind, make sure that the doctor knows that you are being treated with Baclofen Aguettant.
- The presence of a PEG tube increases the incidence of infections in children.
- If you have reduced circulation of liquid contained in the brain and spinal cord as a result of obstructed passage, for example caused by inflammation or injuries.
- Contact your doctor immediately if you think that Baclofen Aguettant is not working as well as usual. It is important to make sure that there are no problems with the pump.
- Treatment with Baclofen Aguettant must not stop suddenly because of the risk of withdrawal effects. You must make sure that you do not miss those hospital visits when the pump reservoir is being refilled.
- Your doctor may want to give you a check up from time to time while you are being treated with Baclofen Aguettant.
- **Tell your doctor** immediately if you get any of these symptoms during treatment with Baclofen Aguettant:

If you have pain in your back, shoulders, neck and buttock during the treatment (a type of spinal deformity called scoliosis).

Children and adolescents

Baclofen Aguettant is not recommended for children under 4 years. Children should be of sufficient body mass to accommodate the implantable pump for chronic infusion. There is very limited clinical data regarding the safety and efficacy of the use of Baclofen Aguettant in children under the age of four year.

Other medicines and Baclofen Aguettant

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can interfere with your treatment. Remind your doctor or nurse if you are taking any of the following:

- Other medicines for your spastic condition
- Medicines to treat depression
- Medicines for high blood pressure
- Medicines for Parkinson's disease
- Strong pain relief medicines, such as morphine
- Medicines which slow down the function of the central nervous system, such as sleep inducing medicines

Baclofen Aguettant and alcohol

- Avoid drinking alcohol during treatment with Baclofen Aguettant as this may lead to an undesirable intensification or unpredictable change in the effects of the medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

There is limited experience on the use of intrathecal baclofen during pregnancy. Baclofen Aguettant should not be used during pregnancy, unless the doctor finds it necessary and the expected benefit for the mother outweighs the potential risk for the child.

Breast-feeding

Baclofen Aguettant passes into breast milk, but in amounts so small that the infant will probably not experience any undesirable effects. Ask your doctor for advice before using Baclofen Aguettant during breast-feeding

Driving and using machines

Some people may feel drowsy and/or dizzy or have problems with their eyes while they are being treated with Baclofen Aguettant. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machinery) until these effects have worn off.

Baclofen Aguettant contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per unit volume, that is to say essentially “sodium-free”.

3. HOW TO USE BACLOFEN AGUETTANT

Baclofen Aguettant is administered by intrathecal injection. This means that the medicine is injected directly into the spinal fluid. The dose needed varies from person to person depending on their condition, and the doctor will decide what dose you need after he/she has tested your response to the drug.

First of all the doctor will find out, by giving you single doses of Baclofen Aguettant, whether it is suitable for you. Usually, this test dose is administered via lumbar puncture or an intrathecal (spinal) catheter, in order to provoke a response. During this period your heart and lung functions will be closely monitored. If your symptoms improve, a special pump which can deliver the drug continuously, will be implanted into your chest or abdominal wall. The doctor will give you all of the information you need to use the pump and to get the correct dosage. Make sure that you understand everything.

The final dose of Baclofen Aguettant depends on how each person responds to the drug. You will be started on a low dose, and this will be increased gradually over a few days, under the supervision of the doctor, until you are having the dose which is right for you. If the starting dose is too high, or if the dose is increased too quickly, you are more likely to experience side effects.

It is extremely important that you keep your appointment with the doctor to refill the pump.

To avoid unpleasant side effects which may be serious and even life-threatening, it is important that your pump does not run out. The pump must always be filled by a doctor or nurse, and you must make sure that you do not miss your clinic appointments.

Efficacy of baclofen intrathecal has been demonstrated in clinical studies using a pump system to deliver baclofen directly into the spinal fluid (infusion systems). An EU certified pump system is implanted beneath your skin, mostly into the abdominal wall. The pump stores and releases the right amount of medicine through the catheter directly into your spinal fluid.

During long-term treatment some patients find that Baclofen Aguettant becomes less effective. You may require occasional breaks in treatment. Your doctor will advise you what to do.

Baclofen Aguettant 10mg/5ml:

To open the package of Baclofen Aguettant Intrathecal, please hold the package with the two hands and turn the edges in opposite way until the opening.

If treatment with Baclofen Aguettant is interrupted

It is very important that you, and those caring for you, are able to recognise signs of Baclofen Aguettant withdrawal. These signs may appear suddenly or slowly for example because the pump or delivery system is not working properly.

The signs of withdrawal are:

- increased spasticity, too much muscle tone
- difficulty with muscle movements
- increase in heart rate or pulse
- itching, tingling, burning sensation or numbness (paraesthesia) in your hands or feet
- palpitations
- anxiety
- high body temperature
- low blood pressure
- altered mental conditions for example agitation, confusion, hallucinations, abnormal thinking and behaviour, convulsions

If you have any of the above signs, tell your doctor straight away. These signs may be followed by more serious side effects unless you are treated immediately.

If you use more Baclofen Aguettant than you should

It is very important that you, and anyone caring for you, can recognise the signs of overdose. These may appear if the pump is not working properly, and you must tell the doctor straight away.

Signs of overdose are:

Unusual muscle weakness (too little muscle tone)

Sleepiness

Dizziness or light-headedness

Excessive salivation

Nausea or vomiting

Difficulty in breathing Convulsions

Loss of consciousness

Abnormally low body temperature

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Baclofen Aguettant can cause side effects, although not everybody gets them.

The side effects listed below have been reported:

Very common: may affect more than 1 in 10 people

Feeling tired, drowsy or weak.

Common: may affect up to 1 in 10 people

Feeling lethargic (having no energy)

Headache, dizziness or light-headedness

Pain, fever or chills

Seizures

Tingling hands or feet

Problems with eyesight

Slurred speech

Insomnia

Breathing difficulties, pneumonia

Feeling confused, anxious, agitated or depressed

Low blood pressure (fainting)

Feeling or being sick, constipation and diarrhoea

Loss of appetite, dry mouth or excessive saliva

Rash and itching, swelling of the face or hands and feet

Urinary incontinence, or problems when urinating

Cramps

Sexual problems in men, e.g. impotence.

Uncommon: may affect up to 1 in 100 people

Feeling abnormally cold

Memory loss

Mood swings and hallucinations, feeling suicidal

Stomach ache, difficulty in swallowing, loss of taste, dehydration

Loss of muscle control

Raised blood pressure

Slow heart beat

Deep vein thrombosis

Flushed or pale skin, excessive sweating

Hair loss.

Other side effects (how often they happen is not known)

Restlessness

Abnormally slow breathing rate.

Increase in sideways curvature of the spine (scoliosis).

There have been reports of problems associated with the pump and delivery system such as infections, inflammation of the lining around the brain and spinal cord (meningitis) or inflammation at the tip of the delivery tube.

Reporting of side effects

If you get any side effects, talk to your doctor 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 Website:

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 BACLOFEN AGUETTANT

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

Do not use Baclofen Aguettant after the expiry date which is stated on the outer carton and on the ampoule. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Store in the original package in order to protect from light.

From a microbiological point of view, unless the method of opening and dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use Baclofen Aguettant if you notice that the solution is not clear and free from particles.

As it is limited to hospital use the waste drug elimination is carried out directly by the hospital. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Baclofen Aguettant contains

The active substance is baclofen

Baclofen Aguettant 2mg/ml solution for infusion in 5ml ampoule

1 ampoule with 5 ml of solution contains 10 mg of baclofen.

1 ml of solution for infusion contains 2.0 mg of baclofen.

Baclofen Aguettant 2mg/ml solution for infusion in 20ml ampoule

1 ampoule with 20 ml of solution contains 40 mg of baclofen.

1 ml of solution for infusion contains 2.0 mg of baclofen

The other ingredients are sodium chloride (3.5 mg/ml sodium) and water for injections.

What Baclofen Aguettant looks like and contents of the pack

Solution for infusion

Clear and colorless solution in ampoules.

Baclofen Aguettant 2mg/ml solution for infusion in 5ml ampoule

Type I clear colorless glass 5 mL ampoules with score-break and violet colored ring marker.

Box of 1, 5 and 10 ampoules containing 5 ml of solution.

Baclofen Aguettant 2mg/ml solution for infusion in 20ml ampoule

Type I clear colorless glass 20 mL ampoules with score-break and green colored ring marker.

Box of 1 ampoule containing 20 ml of solution.

Baclofen Aguettant 2mg/ml solution for infusion in 5ml ampoule in sterile plastic blister

Type I clear colorless glass 5 mL ampoules with score-break and violet colored ring marker, packaged in sterile plastic blister.

Box of 5 and 10 ampoules containing 5 ml of solution.

Baclofen Aguettant 2mg/ml solution for infusion in 20ml ampoule in sterile plastic blister

Type I clear colorless glass 20 mL ampoules with score-break and green colored ring marker, packaged in sterile plastic blister.

Box of 1 ampoule containing 20 ml of solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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