



solution for infusion

2 mg/ml**Baclofen Aguettant****Baclofen Aguettant****2 mg/ml**

solution for infusion



AGUETTANT

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**Baclofen Aguettant 2 mg/ml, solution for infusion
{baclofen}

Please read this product information carefully before you or your child is given Baclofen since it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

The name of this medicinal product is **Baclofen Aguettant 2 mg/ml solution for infusion**, but will be referred as Baclofen throughout the whole leaflet.

In this leaflet:

1. What Baclofen is and what it is used for
2. Before you take Baclofen
3. How to use Baclofen
4. Possible side effects
5. How to store Baclofen
6. Further information

1. WHAT BACLOFEN IS AND WHAT IT IS USED FOR

Your doctor has decided that you or your child needs this medicine to help treat your condition.



Baclofen is intended for adults and children of 4 years and above and is used to reduce and relieve the excessive tension in your muscles (spasms) occurring in various illnesses such as cerebral palsy, multiple sclerosis, spinal cord diseases, cerebrovascular accidents, and other nervous system disorders.

This injection is used in people who haven't responded to oral medicines or who get unacceptable side effects when they take baclofen by mouth.

2. BEFORE YOU TAKE BACLOFEN**Children and adolescents:**

Baclofen formulation is intended for children of 4 years and above.

Do not use Baclofen

- if you are allergic to baclofen or to any of the other ingredients of Baclofen (These are listed at the end of the leaflet)
- if you suffer from epilepsy refractory to therapy
- Baclofen should not be administered by any route other than intrathecal (into the spinal canal)

Take special care with Baclofen

- 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 (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 or lung disease
- 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 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.
- The presence of a PEG tube increase the incidence of infections in children.
- If you have a slowed cerebrospinal fluid circulation the effect of Baclofen may be reduced.
- Contact your doctor immediately if you think

that Baclofen is not working as well as usual.

It is important to make sure that there are no problems with the pump.

- Treatment with Baclofen 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.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines can interfere with your treatment.

Remind your doctor or nurse if you are taking any of the following:

- Other medicines for your spasticity condition
- Antidepressants
- Medicines for high blood pressure
- Other drugs which also affect the kidney, e.g. ibuprofen
- Medicines for Parkinson's disease
- Medicines for epilepsy
- Opiates for pain relief
- Medicines which slow down the nervous system, e.g. anti-histamines and sedatives. (Some of these can be bought over-the-counter)

Using Baclofen with food and drink

- Be careful when drinking alcohol - it may affect you more than usual.

Fertility, pregnancy and breast-feeding

Ask your doctor or nurse for advice before taking any medicine.

There are no adequate and sufficiently controlled studies in pregnant women. Baclofen crosses the placental barrier. Baclofen must not be used during pregnancy, unless the potential benefits outweigh the possible risks to the foetus.

Lactation

It is not known whether measurable levels of the product can be detected in the maternal milk of lactating mothers treated with Baclofen. At oral therapeutic doses, the active substance passes into breast milk, but in amounts so small that the infant will probably not experience any undesirable effects.

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. 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.

Important information about some of the ingredients of Baclofen

This medicinal product contains less than 1 mmol sodium (23 mg) per maximum daily dose, so it is essentially "sodium-free".

3. HOW TO USE BACLOFEN

Baclofen 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, 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 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.

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.

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

Baclofen is not suitable for all children. The doctor will decide.

Efficacy of baclofen intrathecal has been demonstrated in controlled randomised studies

with infusion systems. EU certified pumps can be used as implantable administration system: a refillable reservoir is implanted beneath the skin, mostly into the abdominal wall. This system is connected to an intrathecal (spinal) catheter that passes subcutaneously into the subarachnoid space. Other pumps, known to be suitable for intrathecal baclofen administration based on experience, may be used.

If you use more Baclofen 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 stop using Baclofen

You should not stop treatment suddenly. If the doctor decides to stop your treatment, the dose will be reduced gradually to prevent withdrawal symptoms such as muscle spasms and increased muscle rigidity, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, feeling persecuted or convulsions (fits). On rare occasions these symptoms could be life-threatening. If you or your carers notice any of these symptoms, contact your doctor immediately just in case something has gone wrong with the pump or delivery system.

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 can cause side effects, although not everybody gets them.

Stop taking the medicine and/or seek urgent medical advice if you present any of the side effects below:

Common: may affect up to 1 in 10 people

- Seizures
- Pneumonia

Uncommon: may affect up to 1 in 100 people

- Feeling suicidal
- Deep vein thrombosis

The side effects listed below have also 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
- Tingling hands or feet
- Problems with eyesight
- Slurred speech
- Insomnia
- Breathing difficulties
- 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
- Stomach ache, difficulty in swallowing, loss of taste, dehydration
- Loss of muscle control
- Raised blood pressure
- Slow heart beat
- Flushed or pale skin, excessive sweating
- Hair loss.

There have been rare (may affect up to 1 in 1,000 people) reports of problems associated with the pump and delivery system. There are sometimes (frequency cannot be estimated from the available data) adverse events associated with the delivery system e.g. infections or meningitis, in particular the presence of a PEG tube increased the incidence of deep infections in children.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to adjust the dose or give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This included any possible side effects not listed in this leaflet. You can also

report side effects directly via the Yellow Card Scheme at: <http://yellowcard.mhra.gov.uk/>

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BACLOFEN

Keep all medicines out of the reach and sight of children.

Do not use Baclofen after the expiry date {month/year} 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 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. FURTHER INFORMATION

What Baclofen contains

The active substance is baclofen

Baclofen Aguetant 2 mg/ml solution for infusion in 5 ml 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 Aguetant 2 mg/ml solution for infusion in 20 ml 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 looks like and contents of the pack

Solution for infusion

Clear and colourless solution in ampoules.

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

Type I clear colourless glass 5 ml ampoules with score-break and violet colour ring marker. Box of 5 and 10 ampoules containing 5 ml of solution.

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

Type I clear colourless glass 20 ml ampoules with score-break and green colour ring marker. 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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