Package leaflet: Information for the user

Gablofen 0.05 mg/ml solution for injection/infusion in pre-filled syringe
Gablofen 0.5 mg/ml solution for injection/infusion in pre-filled syringe
Gablofen 1 mg/ml solution for injection/infusion in pre-filled syringe
Gablofen 2 mg/ml solution for injection/infusion in pre-filled syringe

Gablofen 0.5 mg/ml solution for injection/infusion
Gablofen 1 mg/ml solution for injection/infusion
Gablofen 2 mg/ml solution for injection/infusion
Baclofen

Read all of this leaflet carefully before you are given this medicine because it 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 pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Gablofen is and what it is used for

Gablofen contains the active substance Baclofen. It belongs to the group of medicines called muscle relaxants.

Gablofen is administered by injection into the spinal canal directly into the spinal fluid (intrathecal injection) and relieves severe muscle rigidity (spasticity).

Gablofen 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

Gablofen 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.

If you do not feel better, or feel worse, contact your physician.

2. What you need to know before you are given Gablofen

Do not use Gablofen
- if you are **allergic** to baclofen or any of the other ingredients of this medicine (listed in section 6)
- if you have untreatable **epilepsy**
- by any **other route of administration than** via the **spinal canal**

Warnings and precautions
Talk to your doctor before you are given Gablofen if you are/have:
- any infection

- had a head injury; for patients with spasticity due to head injury, it is recommended not to proceed to intrathecal Gablofen therapy until the symptoms of spasticity are stable and can be reliably assessed
- had autonomic dysreflexia: a reaction of the nervous system to overstimulation, causing sudden severe high blood pressure
- reduced circulation of liquid contained in the brain and spinal cord as a result of obstructed passage, for example caused by inflammation or injuries
- treatable epilepsy
- had a stomach or intestinal ulcer
- overactive bladder sphincter muscle
- acute or chronic confusional states
- psychotic disorder, or schizophrenia (mental disease)
- Parkinson's disease
- reduced kidney function or a liver disease
- inadequate blood flow in the brain (cerebrovascular insufficiency)
- heart or breathing difficulties
- Monitoring of heart and breathing function is essential during the initial test phase, particularly if you have heart or breathing difficulties.
- scoliosis (increase in sideways curvature of the spine)
- diabetes
- to undergo an operation

Contact your doctor immediately if you think that Gablofen is not working as well as usual. It is important to make sure that there are no problems with the pump.

If you find yourself thinking of harming yourself or taking your own life at any time, talk to your physician immediately or go to a hospital. Also ask a family member or close friend to tell you if he or she is concerned about any changes in your behavior and ask him or her to read this package leaflet.

You will be monitored closely in a fully equipped and staffed environment during the screening phase and dose-finding period immediately following pump implant. You will regularly be assessed for your dosage requirements, for possible side effects or evidence of infection. The functioning of the delivery system will also be checked.

Treatment with Gablofen must not stop suddenly because of the risk of withdrawal effects. Make sure that you do not miss hospital visits when the pump reservoir is being refilled.

Children
Gablofen is **not recommended for children under 4 years**. Older children must have sufficient body mass to accommodate the implantable pump. There is limited clinical data in children under the age of four.

Elderly patients
Some patients over the age of 65 years have been treated with intrathecal baclofen during the clinical trials without specific problems. Experience with baclofen tablets shows however, that this patient group may be more susceptible to side effects. Older patients should therefore be carefully monitored for the occurrence of side effects.

Other medicines and Gablofen
Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription.

Inform your doctor if you are using any of the following medicines as they can affect or be affected by Gablofen:
- other medicines to treat muscle spasm condition
  If possible, your doctor may slowly discontinue other medicines which treat muscle spasm.
- medicines to treat depression

- medicines to treat high blood pressure
- levodopa, carbidopa: medicines to treat Parkinson's disease
- strong pain relief medicines, such as morphine
- medicines which slow down the function of the central system, such as sleep inducing medicines
- other medicines administered into the spine
- Administration of other medicines into the spine is not recommended during Gablofen treatment.

Concomitant use of general anaesthetics may increase the risk of cardiac disturbances and seizures.

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

Pregnancy, breast-feeding and fertility
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.

There is limited experience on the use of intrathecal baclofen during pregnancy or while breast-feeding. Gablofen should not be used during pregnancy or while breast-feeding, unless the expected benefit for the mother outweighs the potential risk for the child. Gablofen passes into breast milk, but low levels are expected after intrathecal administration. Consequently, Gablofen can be used during breast-feeding.

Driving and using machines
During treatment with Gablofen your ability to drive or use machines may be considerably impaired. Some people may feel drowsy, dizzy, have problems with their eyes, difficulties in controlling movements or have hallucinations while being treated with Gablofen. Do not drive or anything that requires you to be alert until these effects have worn off, if this applies to you. Before driving or using machines you should consult your physician.

Gablofen contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

However, if Gablofen is diluted in sodium chloride solution, the sodium content will be higher.

3. How to use Gablofen

Gablofen may **only** be administered by a specially qualified doctor.

The dose varies, dependent upon each person's condition. The doctor will decide your dose after testing your response to this medicine.
Firstly, the doctor will give you single doses of Gablofen, to find out if it is suitable for you. During this period your heart and lung functions will be closely monitored. If your symptoms improve, a special pump which continuously delivers Gablofen will be implanted into your chest or abdominal wall. The doctor will provide you with all necessary instructions for using the pump and dosage information. Make sure that you understand everything.

Your dose depends upon your response to the medicine. Beginning with a low dose, this is gradually increased over a few days under doctor's supervision, until you have the right dose.
Side effects are more likely if the starting dose is too high or the dose is increased too quickly. To avoid these effects, which may be serious, it is important that your pump does not run out. Ensure that you do not miss your hospital appointments.

It is extremely important that you keep your appointments with the doctor to refill the pump, otherwise spasms may recur because you are not getting a high enough dose of Gablofen. Your muscle spasms may worsen as a result.

If your muscle spasticity is not improving or if you start having spasms again, either gradually or suddenly, **contact your doctor immediately**.

If treatment with Gablofen is interrupted
It is very important that you, and those caring for you, are able to recognise signs of Gablofen withdrawal. These may appear suddenly or slowly for example because the pump is not working properly due to battery problems, catheter problems or alarm dysfunction.
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
- priapism (persistent painful erection of the penis)
- 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.

Route of administration
Gablofen may only be administered into the spinal canal (intrathecal use).

Duration of use
To be decided by the doctor.

During long-term treatment, some patients find that Gablofen becomes less effective. Your doctor may recommend occasional breaks in treatment to counteract this.

If you are given more Gablofen than you should

It is very important that you and your carer can recognise the signs of overdose. This may occur if the pump is not working properly.

Inform your doctor immediately if this applies to you or you experience any overdose signs, such as:
- unusual muscle weakness
- sleepiness, clouding or loss of consciousness
- dizziness, light-headedness
- excessive salivation, abnormal low body temperature
- nausea or vomiting
- breathing difficulties, respiratory arrest
- seizures

Please keep in mind that pump malfunctions such as problems with the battery or catheter, faulty alarm function or device malfunction may lead to the dose being too high or too low.

If you stop using Gablofen
If this medicine must be stopped, this may only be done by your doctor who will reduce the dose gradually to avoid side effects. Suddenly stopping intrathecal Gablofen can cause withdrawal symptoms which in some cases have proven fatal.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
These occur more often at the start of treatment during your hospital stay, but they may also occur later. Many of these side effects are also known to be associated with the specific medical condition for which you are being treated.
Side effects can occur with the following frequencies:

Very common, may affect more than 1 in 10 people
- drowsiness
- reduced muscle tension

Common, may affect up to 1 in 10 people
- sedation, dizziness, light-headedness
- pain, fever, chills
- abnormal sensation such as tingling
- problems with eyesight with vision blurred or double-vision
- slurred speech
- lethargy, weakness
- breathing difficulties (respiratory depression, dyspnoea, bradypnoea), lung inflammation (aspiration pneumonia)
- sleeplessness
- confusion, disorientation, anxiety, restlessness, depression
- low blood pressure
- constipation, diarrhoea
- dry mouth, decreased appetite, excessive saliva
- rash, itching
- tissue swelling in the face, hands or feet
- urinary incontinence
- increased muscle tension, muscle weakness
- sexual problems, such as impotence

The following side effects occur more frequently in patients with cerebral spasticity:
Seizures, headache, nausea, vomiting and difficulties in urinating

Uncommon, may affect up to 1 in 100 people
- feeling abnormally cold
- involuntary eye movement (nystagmus)
- difficulties in controlling movements (ataxia)
- reduced memory
- disturbed mood, euphoria, paranoia, hallucinations, suicidal thoughts and attempts
- bowel obstruction, difficulty in swallowing, loss of taste, dehydration
- high blood pressure, slow heartbeat
- deep vein thrombosis
- flushed or pale skin, excessive sweating
- hair loss

Rare, may affect up to 1 in 1000 people
- Life-threatening withdrawal symptoms due to drug delivery failure.

Not known, frequency cannot be estimated from the available data
- Scoliosis (increase in sideways curvature of the spine)
- Erectile dysfunction

For a description of the signs of withdrawal, see "If treatment with Gablofen is interrupted".

For a description of the signs of overdose, see "If you are given more Gablofen than you should".

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 pharmacist**. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via 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 Gablofen

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

Do not use this medicine after the expiry date which is stated on the outer carton and on the pre-filled syringe.
Do not use this medicine after the expiry date which is stated on the outer carton and on the vial.
The expiry date refers to the last day of that month.

Do not store above 30°C. Do not freeze.

After first opening: the product should be used immediately.

Do not use this medicine if you notice that the solution is not clear or free from particles.
As it is limited to hospital use the disposal of unused medicine is carried out directly by the hospital.

6. Contents of the pack and other information

What Gablofen contains
- The active substance is baclofen.
- *Gablofen 0.05 mg/ml*
  Each ml contains 0.05 mg (50 micrograms) baclofen.
  Each 1 ml pre-filled syringe contains 0.05 mg (50 micrograms) baclofen.

  Gablofen 0.5 mg/ml
  Each ml contains 0.5 mg (500 micrograms) baclofen.
  Each 20 ml pre-filled syringe contains 10 mg (10000 micrograms) baclofen.
  Each 20 ml vial contains 10 mg (10000 micrograms) baclofen.

  Gablofen 1 mg/ml
  Each ml contains 1 mg (1000 micrograms) baclofen.
  Each 20 ml pre-filled syringe contains 20 mg (20000 micrograms) baclofen.
  Each 20 ml vial contains 20 mg (20000 micrograms) baclofen.

  Gablofen 2 mg/ml
  Each ml contains 2 mg (2000 micrograms) baclofen.

Each 20 ml pre-filled syringe contains 40 mg (40000 micrograms) baclofen.
Each 20 ml vial contains 40 mg (40000 micrograms) baclofen.

- The other ingredients are sodium chloride and water for injection.

What Gablofen looks like and contents of the pack
Gablofen is a clear, colourless solution for injection.

<Gablofen 0.05 mg/ml> Gablofen is available in packs containing one syringe of 1 ml.
<Gablofen 0.5, 1 and 2 mg/ml > Gablofen is available in packs containing one syringe of 20 ml.
<Gablofen 0.5, 1 and 2 mg/ml > Gablofen is available in packs containing one vial of 20 ml.

Marketing Authorisation Holder and Manufacturer

- **Marketing Authorisation Holder**

Piramal Critical Care Limited, Suite 4, Ground Floor, Heathrow Boulevard - East Wing, 280 Bath Road, West Drayton, UB7 0DQ, United Kingdom, Tel : 00441670562400

- **Manufacturer**
  Laboratoire Aguettant, 1 rue Alexander Fleming, Parc Scientifique Tony Garnier, LYON, 69007, France

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	SPACYR
Denmark	Gablofen
France	SPACYR
Germany	Gablofen
Italy	Baclofene Piramal
Netherlands	Gablofen
Spain	SPACYR
Sweden	Gablofen
United Kingdom	Gablofen

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The following information is intended for medical and healthcare professionals only:

The complete SmPC is provided in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this medicinal product.