

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Bacentra Intrathecal 0,05 mg/ml, solution for injection

Bacentra Intrathecal 0,5 mg/ml, solution for infusion

Bacentra Intrathecal 2 mg/ml, solution for infusion

Baclofen

Read all of this leaflet carefully before you are given Bacentra Intrathecal

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Bacentra Intrathecal has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Bacentra Intrathecal is and what it is used for
2. What you need to know before you are given Bacentra Intrathecal
3. How to receive Bacentra Intrathecal
4. Possible side effects
5. How to store Bacentra Intrathecal
6. Contents of the pack and other information

1. What Bacentra Intrathecal is and what it is used for

| | |
|--------------------------------|---|
| Applicant | : Umsebe Healthcare |
| Proprietary name (dosage form) | : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion) |
| Strength | : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen |

The active ingredient of Bacentra Intrathecal, baclofen, is a muscle-relaxant medicine. Bacentra Intrathecal 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 conditions such as cerebral palsy, multiple sclerosis, spinal cord diseases, cerebrovascular accidents, brain trauma, and other nervous system disorders. This injection is used in people who have not responded to oral medicines or who get unacceptable side effects when they take baclofen by mouth.

2. What you need to know before you are given Bacentra Intrathecal

You should not be given Bacentra Intrathecal:

- if you are hypersensitive (allergic) to baclofen or any of the other ingredients of Bacentra Intrathecal (listed in section 6).
- if you suffer from epilepsy refractory to therapy.
- if you have porphyria (a genetic condition).
- if you are pregnant and breastfeeding your baby.
- the catheter needed for a continuous infusion should not be inserted if you have any infection in that area.

Bacentra Intrathecal should not be administered by any route other than intrathecal (into the spinal canal).

Warnings and precautions

Tell your doctor or health care provider before you are given Bacentra Intrathecal:

- if you are having any other injections into the spine.
- If you are taking strong pain medication.
- If you are taking any other muscle-relaxing medicines.

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

- if you are suffering from any infection.
- if you had a head injury within the last year.
- if you have epilepsy.
- if you suffer from any mental illness.
- if you have Parkinson's disease.
- 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 suffer from any liver, kidney or lung disease.
- if you have a stomach ulcer or any other problem with your digestion.
- if you have difficulties in urinating.
- if you are being treated for high blood pressure

Take special care if you are receiving Bacentra Intrathecal:

- You, your care-givers and family members should be familiar with the symptoms of under- and over dosing, as well as the procedures to be implemented in the event of overdose (see “If you receive more Bacentra Intrathecal than you should”).
- If you think that Bacentra Intrathecal is not working as well as usual. It is important to make sure that there are no problems with the delivery pump.
- Treatment with Bacentra Intrathecal 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 Bacentra Intrathecal.

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

- If you are going to have an operation of any kind, make sure that the doctor knows that you are being treated with Bacentra Intrathecal, as certain anaesthetics may increase the risk of side effects.

Children and adolescents

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 Bacentra Intrathecal in children under the age of four years.

Other medicines and Bacentra Intrathecal

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

Some medicines can interfere with your treatment. Tell your doctor, nurse or health care provider if you are taking any of the following:

- Other medicines used to treat your spastic condition, including muscle relaxing medicines.
- Medicines used to treat depression or mental illness.
- Medicines to treat high blood pressure.
- Medicines used to treat Parkinson's disease.
- Medicines used to treat epilepsy.
- Strong pain medication called opiates, e.g. morphine

Bacentra Intrathecal with food, drink and alcohol

Be careful when drinking alcohol whilst receiving Bacentra Intrathecal, as it may affect you more than usual.

| | | |
|--------------------------------|---|---|
| Applicant | : | Umsebe Healthcare |
| Proprietary name (dosage form) | : | Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion) |
| Strength | : | Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen |

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not receive Bacentra Intrathecal if you are pregnant or breastfeeding, as there are no adequate and sufficiently controlled studies in pregnant and lactating women. Baclofen, the active ingredient, crosses the placental barrier, which could lead to exposure of your unborn baby to the medicine. It is not known whether measurable levels of baclofen can be detected in breast milk treated with Bacentra Intrathecal. Orally administered baclofen can pass into breast milk.

Driving and using machines

Some people feel drowsy and/or dizzy or have problems with their eyes while they are being treated with Bacentra Intrathecal. 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.

Bacentra Intrathecal contains sodium

Bacentra Intrathecal contains 3,5 mg/ml sodium and as such, Bacentra Intrathecal contains less than 1 mmol sodium (23 mg) per maximum daily dose, so it is essentially “sodium-free”.

3. How to receive Bacentra Intrathecal

You will not be expected to give yourself Bacentra Intrathecal. It will be given to you by a person qualified to do so.

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

Bacentra Intrathecal is administered via 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. Your doctor will decide what dose you need after he/she has tested your response to Bacentra Intrathecal.

Your treatment will start off with your doctor testing to see whether Bacentra Intrathecal is suitable for you by giving you a single intrathecal injection. Usually, this test dose is administered via lumbar puncture or an intrathecal (spinal) catheter into the spinal fluid, in order to see how you respond to Bacentra Intrathecal. During this test period, your heart and lung functions will be closely monitored.

If it has been established that you responded well to the Bacentra Intrathecal test dose, and that Bacentra Intrathecal is suitable to treat your condition, a special refillable delivery pump, which will be filled with Bacentra Intrathecal, will be implanted beneath your skin into your chest or abdominal wall. This delivery system is connected to an intrathecal (spinal) catheter that passes under the skin into the subarachnoid space, which contains your spinal fluid. Your 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.

During the initial treatment with the delivery pump, your doctor will continually adjust the dose of Bacentra Intrathecal delivered to you by the delivery pump. You will be started on a low dose, which will be increased gradually over a few days under the supervision of your doctor, until the correct dose has been established for you. The final dose of Bacentra Intrathecal will depend on how you respond to the medicine.

To avoid unpleasant side effects which may be serious and even life-threatening, it is important that your pump does not run out of medicine. The pump must always be filled by a

| | | |
|--------------------------------|---|---|
| Applicant | : | Umsebe Healthcare |
| Proprietary name (dosage form) | : | Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion) |
| Strength | : | Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen |

doctor or suitable qualified healthcare professional. You must make sure that you do not miss your hospital appointments to have your pump refilled.

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

If you receive more Bacentra Intrathecal than you should

Since a health care provider will administer this medicine, he/she will control the dosage. However, in the event of overdose, your doctor will manage the overdose.

It is very important that you, your family and anyone caring for you, can recognise the signs of overdose, as they may be serious and can lead to death. The signs of overdose may appear if the delivery pump is not working properly or other medicines have been taken during treatment with Bacentra Intrathecal, which have resulted in a baclofen overdose. The signs of overdose may appear suddenly or gradually.

You must tell the doctor immediately if you notice any of the following:

- Breathing difficulty or being unable to breathe
- Coma
- Unusual muscle weakness (too little muscle tone)
- If you have uncontrollable shock-like jerks of muscles or groups of muscles
- Abnormal or absent reflexes (hyporeflexia or areflexia)
- Sleepiness or general feeling of weakness
- Dizziness or light-headedness
- Epileptic seizures (fits)

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

- Loss of consciousness
- Confusion
- Hallucinations
- Agitation
- Accommodation disorders (difficulty to focus on the surroundings)
- Absence of reflex of the pupils in the eye
- Low or high blood pressure
- Slow or fast heart rate
- Abnormally low body temperature
- Diarrhoea
- Excessive salivation
- Nausea or vomiting

If you did not receive Bacentra Intrathecal

Since a health care provider will administer Bacentra Intrathecal, it is unlikely that the dose will be missed.

Effects when treatment with Bacentra Intrathecal is stopped

Treatment with Bacentra Intrathecal should never be stopped immediately, unless in an emergency, as determined by your doctor.

If treatment with Bacentra Intrathecal is to be stopped, the dose will be gradually reduced by your doctor so as to prevent withdrawal symptoms, which may include muscle spasms and increased muscle rigidity, pruritus (itchy sensation of the skin), pins and needles sensation of the skin, low blood pressure, increased body temperature, confusion and epileptic seizures (fits). On rare occasions these symptoms could be life-threatening. If you, your family or your

| | | |
|--------------------------------|---|---|
| Applicant | : | Umsebe Healthcare |
| Proprietary name (dosage form) | : | Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion) |
| Strength | : | Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen |

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 relating to your treatment with Bacentra Intrathecal, ask your doctor or healthcare professional.

4. Possible side effects

Bacentra Intrathecal can have side effects.

Not all side effects reported for Bacentra Intrathecal are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, tell your doctor, nurse or healthcare professional immediately or go to the casualty department of your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Bacentra Intrathecal. You may need urgent medical attention.

The following frequent side effects have been observed

- Breathing difficulties, chest tightness, pneumonia

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

- Epileptic seizures (fits)
- Feeling confused/disorientated, anxious, agitated or depressed
- Headache, dizziness or light-headedness
- Feeling tired, drowsy or weak
- Feeling lethargic (having no energy)
- Insomnia (difficulty to sleep)
- Finding it difficult to concentrate
- Tingling hands or feet
- Slurred speech
- Problems with eyesight
- Low blood pressure
- Vomiting, nausea (feeling like vomiting)
- Constipation or diarrhoea
- Loss of appetite
- Dry mouth or excessive saliva
- Rash and itching of the skin
- Swelling of the face or hands and feet (facial or peripheral oedema)
- Unusual muscle weakness (too little muscle tone)
- Uncontrollable shock-like jerks of muscles or groups of muscles
- Difficulty to maintain balance
- Urinary incontinence (not being able to control when you urinate) or being unable to urinate
- Sexual problems in men, e.g. impotence.
- Pain, fever or chills

The following less frequent side effects have been observed

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

- Dehydration
- Mood swings and hallucinations, feeling suicidal
- Loss of coordination (ataxia)
- Memory loss
- Uncontrollable eye movements (nystagmus)
- Slow heart rate (bradycardia)
- Raised blood pressure
- Deep vein thrombosis (the forming of a blood clot in a deep vein in the body)
- Flushed or pale skin
- Cerebrovascular disorder (a conditions that affects the blood vessels in the brain)
- Ileus (a condition which makes it difficult to empty your bowel)
- Difficulty in swallowing
- Loss of taste
- Hair loss
- Excessive sweating
- Feeling abnormally cold
- Septicaemia (an infection in which a large amount of bacteria is present in the blood)
- Subdural haemorrhage (bleeding between the skull and brain)
- Accidental injury
- Weight loss
- Potentially life-threatening withdrawal symptoms (as a result of sudden interruption of medicine delivery)

The following side effects have been observed, but their frequency is unknown (how often they happen is not known)

- Restlessness (dysphoria)

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

- Scoliosis (a condition where the spine curves sideways)
- Erectile dysfunction

There have been rare reports of problems associated with the pump and delivery system, which include infections, a collection of immune cells at the tip of delivery tube, dislodgement/kink/rupture of the delivery tube, meningitis, seroma (blood plasma that has leaked out of small blood vessels), bleeding, pump malfunction, cerebrospinal fluid leakage, skin ulcers and overdose or underdose. In one report, the presence of a polyethylene glycol (PEG) tube increased the incidence of deep infections in children.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store Bacentra Intrathecal

Store all medicines out of sight and reach of children.

Store at or below 30 °C.

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 Bacentra Intrathecal if you notice that the solution is not clear and free from particles.

Every ampoule is for single-use only. Any remaining product must be disposed of.

Bacentra Intrathecal must not be re-sterilized.

6. Contents of the pack and other information

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

What Bacentra Intrathecal contains

The active substance in Bacentra Intrathecal is baclofen.

Each Bacentra Intrathecal 0,05 ampoule contains 0,05 mg/ml baclofen.

Each Bacentra Intrathecal 0,5 ampoule contains 0,5 mg/ml baclofen.

Each Bacentra Intrathecal 2 ampoule contains 2 mg/ml baclofen.

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

What Bacentra Intrathecal looks like and contents of the pack

Bacentra Intrathecal 0,05 mg/ml is a clear and colourless solution filled into 2 ml (filled to 1 ml) clear Type I glass ampoules.

Bacentra Intrathecal 0,5 mg/ml is a clear and colourless solution filled into 20 ml clear Type I glass ampoules.

Bacentra Intrathecal 2 mg/ml is a clear and colourless solution filled into 5 ml and 20 ml clear Type I glass ampoules.

Bacentra Intrathecal 0,05 mg/ml is presented in a 2 ml (filled to 1 ml) Type I clear, colourless glass ampoule with a score-break and blue coloured ring marker. The ampoules are packed into cardboard boxes in quantities of 5 or 10 ampoules per box. Not all pack sizes may be marketed.

Bacentra Intrathecal 0,5 mg/ml is presented in a 20 ml Type I clear, colourless glass ampoule with a score-break and red coloured ring marker. Each ampoule is packed into a single cardboard box.

Bacentra Intrathecal 2 mg/ml is presented in 5 ml and 20 ml Type I clear, colourless glass ampoules with a score-break and violet (5 ml ampoule) or green (20 ml ampoule) coloured

Applicant : Umsebe Healthcare
Proprietary name (dosage form) : Bacentra Intrathecal 0,05 mg/ml (solution for injection), Bacentra Intrathecal 0,5 mg/ml (solution for infusion) and Bacentra Intrathecal 2 mg/ml (solution for infusion)
Strength : Each ml contains 0,05 mg, 0,5 mg and 2 mg baclofen

ring marker. The 5 ml ampoules are packed into cardboard boxes in quantities of 5 or 10 ampoules per box. Not all pack sizes may be marketed. The 20 ml ampoules are packed into single cardboard boxes.

Holder of Certificate of Registration

Umsebe Healthcare
506 Sunclare Building
21 Dreyer Street, Claremont
Cape Town, 7708
South Africa

Name of Manufacturer: Sintetica SA

This leaflet was last revised in

19 March 2024

Registration numbers

Bacentra Intrathecal 0,05 mg/ml: 54/2.10/0366

Bacentra Intrathecal 0,5 mg/ml: 54/2.10/0367

Bacentra Intrathecal 2 mg/ml: 54/2.10/0368

Access to the corresponding Professional Information

19 March 2024