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Baclofen: Patient drug information

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(For additional information see "Baclofen: Drug information" and see "Baclofen: Pediatric drug information")

Brand Names: US

Gablofen; Lioresal; Ozobax

Brand Names: Canada

APO-Baclofen; Baclofen-10; Baclofen-20; DOM-Baclofen; Lioresal DS [DSC]; Lioresal Intrathecal; Lioresal [DSC]; MYLAN-Baclofen; PMS-Baclofen; RATIO-Baclofen [DSC]; RIVA-Baclofen

Warning

Infusion:

- Unsafe side effects have happened when this drug was stopped all of a sudden. Some of these side effects have been high fever, mental changes, more spasms, and muscle stiffness. Rarely, these side effects have led to very bad muscle problems, organ problems, and death. Avoid stopping this drug all of a sudden without talking with your doctor. Be sure you get your pump refilled on time and you know about the pump alarms and what to do if the pump alarm goes off. Tell your doctor if you have ever had signs of withdrawal while getting baclofen tablets or shot. Call your doctor right away if you have signs of withdrawal.
- Read the package insert for more details.

What is this drug used for?

- It is used to relax muscles.
- It is used to treat spasms in patients with MS (multiple sclerosis) or spinal cord disease.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

All products:

• If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

Infusion:

• If you have an infection.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of side effects. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.
- Talk with your doctor before you use alcohol, marijuana or other forms of cannabis, or prescription or OTC drugs that may slow your actions.
- Use with care in children. Talk with the doctor.
- Taking this drug during pregnancy may lead to withdrawal in the newborn.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

All products:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Very bad dizziness or passing out.
- Feeling confused.
- Change in how often urine is passed.
- Mental, mood, or behavior changes that are new or worse.

Infusion:

- Seizures.
- Change in eyesight.
- Chest pain.
- Muscle pain or weakness.
- Muscle stiffness.
- A burning, numbness, or tingling feeling that is not normal.
- Trouble breathing, slow breathing, or shallow breathing.
- Not able to pass urine or change in how much urine is passed.
- Blood in the urine.
- Hallucinations (seeing or hearing things that are not there).
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Not able to control eye movements.
- A heartbeat that does not feel normal.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Feeling dizzy, sleepy, tired, or weak.
- Trouble sleeping.
- Upset stomach or throwing up.
- Headache.
- Constipation.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

<u>Tablets:</u>

• Take with or without food.

Liquid (solution):

• Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.

Infusion:

• It is given into the spine.

What do I do if I miss a dose?

Liquid and tablets:

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

Infusion:

• Call your doctor to find out what to do.

How do I store and/or throw out this drug?

Tablets:

- Store at room temperature in a dry place. Do not store in a bathroom.
- If you split the tablets, you may need to throw them away after a certain amount of time. Be sure you know how long you can store the split tablets. If you are not sure, call the pharmacist.

<u>Liquid (solution):</u>

• Store in a refrigerator. Do not freeze.

Infusion:

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

All products:

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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