Package Leaflet: Information for the user

BUTOPAN 20 mg/ml Solution for Injection

Applied intramuscularly, subcutaneously or intravenously.

- ***Active ingredients:***
  Each 1ml ampoule contains 20 mg hyoscine butylbromide..
- ***Excipients:***
  Sodium chloride and water for injection.

Read all of this leaflet carefully before you start taking 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.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Tell your doctor that you are using this medicine when you visit your doctor or a hospital.*
- *Always follow the instructions in this leaflet. Do not use* ***lower or higher doses*** *than prescribed.*

What is in this leaflet:

1. What BUTOPAN Ampoule is and what it is used for*?*

BUTOPAN injection contains 20 mg of hyoscine butylbromide in 1 mL of solution as the active ingredient.
BUTOPAN belongs to a group of medicines called 'antispasmodics'.
Each ampoule 1ml contains; 20 mg of hyoscine-N-butylbromide as active ingredient.
BUTOPAN Ampoules are supplied in cartons containing 6 and 100 pieces of 1 ml ampoules..

- BUTOPAN Ampoules are used to relieve sudden and severe pain with cramps (spasm) in the muscles of your:
  - Stomach
  - Gut (intestine)
  - Bladder and the tubes leading to the outside of your body (urinary system)
  - Bile ducts
  - Reproductive organ

BUTOPAN Ampoules can also be used in some diagnostic and therapeutic medical procedures where spasm may be a problem for example when examining the stomach and duodenum with an optical instrument (endoscopy).

2. What you need to know before you use BUTOPAN Ampoules

Do not use BUTOPAN Ampoules if:

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients
- You have an eye problem called glaucoma that causes excessive intraocular pressure and you are not being treated for it.
- You have megacolon (a very enlarged bowel)
- You have something called 'myasthenia gravis' (a very rare muscle weakness problem)
- You have a very fast heart rate
- You have difficulty or pain passing water (urine) such as men with prostate problems
- You have intestinal obstruction due to mechanical obstruction or paralysis of bowel movements in your digestive system.
- You are pregnant, likely to get pregnant or are breast-feeding
- You should not receive this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.
- You have a disease called **megacolon** that causes excessive enlargement of some of the large intestines and is manifested by persistent constipation and enlarged abdomen.

Tell your healthcare provider if you are taking BUTOPAN Injection by the intramuscular route and you are currently being administered anticoagulant drugs (blood thinners) as intramuscular bleeding may occur with this combination. If you are receiving such treatment, BUTOPAN should be injected subcutaneously or intravenously.

Take special care with BUTOPAN Ampoules:

- If you have an undiagnosed disorder called narrow-angle glaucoma (You may have a sudden increase in intraocular pressure after BUTOPAN application. If you have pain, redness, vision loss after BUTOPAN application, contact an ophthalmologist immediately.)
- Sudden hypersensitivity response (anaphylactic shock) was observed following intravenous administration of BUTOPAN. In this case, you should be observed by your doctor during the application of BUTOPAN.
- If your temperature is high (if you have a fever), you should be observed by your doctor, as BUTOPAN application may reduce sweating.

You should not receive this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking this medicine.

Using BUTOPAN with food and drinks

BUTOPAN is not taken orally. Therefore, it does not interact with food and drinks.
BUTOPAN is administered by a healthcare professional by injecting intramuscularly, subcutaneously or intravenously.

Pregnancy
Talk to your doctor or pharmacist before receiving BUTOPAN Ampoules.
If you think you are (or may be) pregnant, you should tell your doctor. BUTOPAN should not be used during pregnancy.
If you notice that you are pregnant during your treatment, talk to your doctor or pharmacist immediately.

Breast-feeding
Talk to your doctor or pharmacist before receiving BUTOPAN Ampoules.
Do not use BUTOPAN if you are breast-feeding.

Driving and using machines
Some people may have sight problems during the use of BUTOPAN. If this happens to you, wait until your sight returns to normal before driving or using any tools or machines. Talk to your doctor before driving or using machines.

Important information about some of the ingredients of BUTOPAN Ampoules

BUTOPAN contains 6.2 mg sodium in 1 ml. This sodium amount is much lower than the limit value (23 mg) which requires precaution. Essentially, this medicinal product is considered "sodium-free".

Taking other medicines
If you are using the following medicines, be sure to inform your doctor, as there is a risk of interacting with BUTOPAN:

When BUTOPAN is used with the following drugs, anticholinergic effects such as dry mouth, constipation, blurred vision, sweating, urine accumulation in the urinary bladder, and acceleration of the heart rate may increase:

- Medicines for depression called 'tetracyclic antidepressants' or 'tricyclic antidepressants'
- Medicines for allergies and travel sickness called 'antihistamines'
- Medicines to control your heart beat such as quinidine or disopyramide
- Amantadine, a drug used in Parkinson's disease
- Other anticholinergic drugs used for breathing problems, such as asthma (eg tiotropium, ipratropium)
- Medicines for severe mental illness such as haloperidol or fluphenazine

- Metoclopramide: It is a dopamine antagonist used to prevent vomiting. When used with BUTOPAN, may result in diminution of the effects of both drugs on the gastrointestinal tract.

- Beta-adrenergic drugs: this druds used to treat high blood pressure, chest pain, heart rhythm disorders and heart attack. The use of beta-adrenergic drugs in combination with BUTOPAN may enhance the effect of increased heart rate caused by beta-adrenergic.

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

3. How to use BUTOPAN?

Instructions for administration and dose/frequency of administration:
BUTOPAN will be administered to you / your child under the supervision of your doctor and by a healthcare professional.

BUTOPAN is usually used in the following dosage.

- Adults and adolescents over 12 years:

1 or 2 ampoules (20 – 40 mg) may be administered by **slow** intravenous, intramuscular or subcutaneous injection several times a day. A maximum daily dose of 100mg should not be exceeded.

- Infants and young children:

In severe cases, 0.3 - 0.6 mg/kg bodyweight, to be administered by slow intravenous, intramuscular or subcutaneous injection several times a day.

BUTOPAN should not be taken on a continuous daily basis or in high doses without your doctor's approval..

Method and route of administration:
BUTOPAN is administered by intramuscularly, subcutaneously or slowly intravenously. BUTOPAN injection is applied by a healthcare professional.

Special age groups:

Infants and children:
In babies and young children, the maximum daily dose should not exceed 1.5 mg per kilogram of body weight.

Use in the elderly:
No dosage adjustment is required in elderly patients.

Special patients:
Reduced kidney/liver functions:
If you have impaired hepatic or renal function, this medicine should be used with caution under the control of a doctor.

If you have the impression that the effect of BUTOPAN is too strong or too weak, you should tell your doctor or pharmacist.

If you used more BUTOPAN than you should have:
Overdose of BUTOPAN injection is unlikely as it is used under medical supervision.

If you think you have been given more BUTOPAN *than you should, tell your doctor or pharmacist.*

If you do receive too much BUTOPAN injection, signs may include drowsiness, dry mouth, redness of the skin, difficulty passing urine, reddening of the skin, decreased gastrointestinal tract movement, sight disturbances، low blood pressure and breathing difficulties.

If you forget to use BUTOPAN
It is important to take your medication dose as your doctor has told you. If you forget to use a

dose of your medicine, use the next dose as soon as you remember. But if it is nearly time for the next dose, skip the forgotten doseand continue your treatment by taking your normal dose. Do not take a double dose to make up for a forgotten dose.

Effects that may occur when treatment with BUTOPAN is terminated
None .

4. What is possible side effects?

Like all medicines, **BUTOPAN** may cause side effects in patients who are sensitive to any of the ingredients of this medicine.

According to the frequency of reported side effects, it is as follows:

Common (less than one in 10 patients, but more than one in 100 patients):

- Impaired ability to adapt to seeing near or far in the eye (accommodation disorders).
- Increased heart rate.
- Dizziness.
- Dry mouth.

Rare (less than one in 1000 patients, but more than one in 10000 patients)

- Skin reactions, skin redness
- Dishidrosis (A Skin Disease Caused By Abnormal Sweating, Especially On The Hands And Feet)
- Skin rash
- Urinary retention
- Severe allergic reaction (rash, itching, swelling of the face, lips, or swelling of the mouth or throat, making it difficult to swallow or breathe).

This is a very serious side effect. You may need an emergency medical intervention or hospitalization. This very serious side effect is rare.

If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects includes any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. In addition, you can report this side effects to Turkey Pharmacovigilance Center by one of the following 2 ways:
1- Online at: www.titck.gov.tr then click on the "Medication Side Effect Report" icon.
2- By calling 0800 314 00 08 (the side-effect notification line).
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store BUTOPAN?

Keep out of the reach and sight of children • Store below 30°C, keep the ampoules in the outer carton in order to protect from light.

Use the medicine in conformity with the expiry date.

• *BUTOPAN Ampoules should not be used after the expiry date which is printed on the carton and ampoules.*

Do not dispose of expired or unused drugs! Give it to the collection system determined by the Ministry of Environment.

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