

PACKAGE LEAFLET: INFORMATION FOR THE USER

Micropaque 1g/mL, oral or rectal suspension

Barium sulphate

Read all of this leaflet carefully before you start using this medicine.

- 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 or pharmacist.

In this leaflet:

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

1. WHAT MICROPAQUE IS AND WHAT IT IS USED FOR

This medicine is for diagnostic use only.

Micropaque is an X-ray contrast media used to highlight areas of your body. It is most commonly used in X-ray or similar medical examinations to help the doctor diagnose problems in your digestive system (throat, stomach and bowels).

This medicine is for the use of children, adults and the elderly.

2. BEFORE YOU USE MICROPAQUE**Do not use Micropaque**

- if you are allergic (hypersensitive) to the active substance (barium sulphate) or any of the other ingredients (refer to the end of this leaflet);
- if you suffer from stomach ulcers, or any other stomach or bowel problem (perforation, obstruction, etc);
- if you have had a surgery or an examination (endoscopy) of the digestive tract within the 7 previous days;
- if you have had a radiotherapy of the digestive tract within the 4 previous weeks.

Tell your doctor if you are suffering from any of these conditions.

Take special care with Micropaque

This medicinal product must not be injected.

Like with all products containing barium sulphate, there is a risk of side effects; they are usually minor but can also be life-threatening. Possible allergic-like reactions may occur in the hours following administration, up to 7 days after administration. They are unforeseeable but the risk of occurrence is increased if you have already had a reaction following previous administration of product containing barium

sulphate (see section 4 "Possible side effects"). If this is the case, you should inform your doctor.

Inform your doctor:

- if you have already experienced a reaction following the administration of the same type of medicinal product;
- if you suffer from asthma;
- in case of constipation or any other problem of the digestive system;
- if you have any difficulty to swallow or to breath;
- if your kidneys do not work properly;
- in case of Hirschsprung's disease (very rare bowel problem affecting the children);
- if you are to undergo other radiological examination in the next few days.

Using other medicines

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

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, may become pregnant, or are breast-feeding.

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

Important information about some of the ingredients of Micropaque

This medicinal product contains:

- Glucose and sucrose in the vanilla/caramel flavour. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sodium (1.76 g per 500 mL suspension). Please take this into consideration if you are on a low salt diet.
- Potassium (170 mg per 500 mL suspension). Please take this into consideration if you have a reduced kidney function or are on a controlled potassium diet.
- "Parahydroxybenzoate" and may cause allergic reactions (possibly delayed).

3. HOW TO USE MICROPAQUE

Always use Micropaque exactly as your doctor has told you. You should check with him/her if you are not sure.

DosageAdults:

The dose will be decided by the doctor depending on the type of examination.

In the Elderly:

The dose will be decided by the doctor depending on the type of examination. Special care should be taken to follow the advice given in this leaflet.

In Children:

The dose will be decided by the doctor as such investigations in children are rare and specialised. It will therefore be tailored to suit the special requirements in each case.

Method of administration

Depending on the part of the digestive system to be examined, you may be given this medicine:

- rectally (into the back passage) as an enema,
- or orally (by mouth) as a drink.

As an enema, the clinic/hospital staff will explain how Micropaque will be used. The medical staff will take care about a right positioning of the administration device.

As a drink, you may need to swallow more than 1 Litre (over 2 pints). It is particularly important to take this medicine exactly as told to do so. You should finish all that you have been given.

You should check with your doctor if you are not sure. If you see other doctors, let them know what medicines you have taken.

If you use more Micropaque than you should

Although you will be given Micropaque in a hospital, and there will be little chance of an overdose, if you think a child or anyone else has swallowed any of it, let the emergency department or hospital staff know immediately.

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.

Side effects can occur at some frequencies which are detailed below:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data

Most side effects are not serious. Side effects reported for Micropaque are mentioned below. Their frequency is not known.

- sudden skin rash, breathing difficulties and fainting (within minutes or days) due to allergic reactions;
- vomiting, diarrhoea, abdominal pain, constipation, feeling bloated, flatulence;
- breathing difficulties;
- dizziness and feeling of imminent loss of consciousness (presyncope);
- urticaria (patches of red skin, severely itching), rash.

In very rare cases the administration of this type of medicinal product can cause the formation of a plug of faeces and barium in the bowel.

In case of perforation of the bowel, barium could leak into the abdomen, and cause potentially abscesses, inflammation or peritonitis. This could require surgery; however, it is an extremely rare complication.

The passage of barium into the blood may be responsible for blockage of blood vessels, shock, important difficulties to breathe and multiple formation of clots in the blood vessels.

If you get any of the side effects, talk to your doctor or health professional. This includes any side effects not listed in this leaflet.

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 the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.

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

5. HOW TO STORE MICROPAQUE

Keep out of the reach and sight of children.

This medicine should be stored below 25°C. Do not freeze it.

Do not use Micropaque after the expiry date which is stated on the container. The expiry date refers to the last day of that month. If you have any medicines that are out of date, return them to your pharmacist or hospital for safe disposal.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist or hospital how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Micropaque contains

- The active substance is barium sulphate (1 g/mL).
- The other ingredients are carmellose sodium, sodium citrate dihydrate, xanthan gum, potassium sorbate, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, vanilla/caramel flavour, saccharin sodium, sulphuric acid, and purified water.

What Micropaque looks like and contents of the pack

Micropaque is a white, thick liquid with a sweet vanilla flavour.

Micropaque is available in bottles of 500 mL or 2,000 mL.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Guerbet
B.P. 57400
95943 Roissy CdG Cedex
FRANCE

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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