PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MultiHance 0,5 M solution for injection

Gadobenic acid

Sugar free.

Read all of this leaflet carefully before you are given MultiHance.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **MultiHance** 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 MultiHance is and what it is used for
2. What you need to know before you receive MultiHance
3. How MultiHance will be administered
4. Possible side effects
5. How to store MultiHance
6. Contents of the pack and other information.

1. What MultiHance is and what it is used for

MultiHance contains the active substance gadobenic acid.

MultiHance is a contrast medium for use in diagnostic magnetic resonance imaging (MRI) improving images of the liver, brain and spine, and breast. It helps your doctor to identify any abnormalities of your liver, brain and spine, and breast.

MultiHance is used in contrast enhanced MR-angiography (MRA) detecting blood flow in patients with suspected or known vascular disease of the stomach arteries.

2. What you need to know before you receive MultiHance

MultiHance should not be given to you or your child if either of you:

- if you are allergic to gadobenic acid or any of the other ingredients of **MultiHance** (see section 6);
- have had a history of allergic or other adverse reactions to gadolinium chelates, especially if you have a history of asthma or other allergic disorders;
- are pregnant or breastfeeding a baby;
- have severely impaired kidney function;
- are younger than 18 years of age, for MRA or MRI of the liver or breast;
- your child is younger than the age of 2 years for MRI of the brain and spine.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection if either of you:

- are sensitive to benzyl alcohol;
- have a heart disease;
- have impaired kidney function;
- you will undergo a liver transplant;
- you have any metal implants such as a pacemaker or aneurism clips;
- you are suffering from epilepsy or have a brain lesion.

MultiHance is only administered in hospitals or clinics.

Children and adolescents

Children under the age of 18 years should not receive **MultiHance** for MRA or MRI of the liver or breast (see beginning of section 2).

Children under the age of 2 years should not receive **MultiHance** for MRI of the brain and spine (see beginning of section 2).

Other medicines and MultiHance

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

It is not known if **MultiHance** interacts with other medicines.

Pregnancy and breastfeeding

If you are pregnant, 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 you receive **MultiHance**.

MultiHance can cross the placenta. It is not known whether it affects the baby.

You should not be given **MultiHance** during pregnancy or if you are breastfeeding as safety has not been established.

You should stop breastfeeding before administration of **MultiHance** and you should not breastfeed your baby for 24 hours after receiving **MultiHance**.

Driving and using machines

MultiHance has no or negligible influence on the ability to drive or use machines. Do not drive or operate any tools or machines until you know how **MultiHance** affects your ability to concentrate or drive.

3. How MultiHance will be administered

You will not be expected to give yourself MultiHance. It will be given to you by a person who is qualified to do so.

MultiHance will be given to you as an intravenous (in a vein) injection by your doctor.

The dosage of **MultiHance** given to you will depend on your medical condition, your body weight and if your liver and kidneys are working properly.

If you receive more MultiHance than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage.

However, in the event of overdosage, your doctor will manage the overdosage.

4. Possible side effects

MultiHance can have side effects.

Not all side effects reported for **MultiHance** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MultiHance**, please consult your health care provider for advice.

If any of the following happens, stop receiving MultiHance and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Headache.
- Nausea.

The following side effects have been reported less frequently:

- Sore throat.
- Tingling of the skin, dizziness, fainting and a change in sense of smell.
- Abnormal heart rhythm, faster or slower heartbeat, high or low blood pressure.
- Runny nose and sneezing.
- Dry mouth or increased spit, changes in taste sensation, diarrhoea, vomiting, upset stomach and abdominal pain.
- Rash and/or hives on the skin and itching, redness of the skin, swelling of the face and increased sweating.

- Back pain and muscle pain.
- Weakness, fever, chills, chest pain, pain- and leakage of fluid at the injection site.
- Increase in the sensitivity to stimuli, tremor, increased pressure in the scull, partial paralysis and convulsion (fits).
- Vision loss.
- Conjunctivitis.
- Noise or ringing in the ears.
- Irregular heartbeat, decrease of oxygen in the heart.
- Flushing of the skin.
- Shortness of breath, laryngospasm, wheezing, fluid build-up in the lungs, cough.
- Constipation, bowel leakage, inflammation of the pancreas.
- Urge to urinate, urine leakage, protein in the urine which may cause more frequent urination, tiredness, swelling in the face, feet and ankles, lack of appetite and muscle cramping at night.
- Injection site inflammation, pain, burning, warmth, redness, coldness, discomfort or rash.

Other side effects where the frequency cannot be determined:

- Loss of consciousness.
- Heart attack, chest pain due to reduced blood flow to the heart.
- Cyanosis (a blue discolouration of the skin).
- Swelling of the larynx (voice box) or mouth, difficulty breathing.
- Swelling or blisters at the injection site.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of **MultiHance**.

5. How to store MultiHance

Store all medicines out of reach of children.

Store at or below 25 °C.

Single dose container. Discard any unused portion.

Do not freeze.

6. Contents of the pack and other information

What MultiHance contains

The active substance is gadobenic acid. Each 1 mL **MultiHance** of solution for injection contains gadobenic acid 334 mg (0,5 M) as the salt dimeglumine gadobenate.

The other ingredients are water for injection.

What MultiHance looks like and contents of the pack

A clear, colourless solution that is free of visible particles in suspension.

10 mL and 20 mL clear colourless glass vials with elastomeric closures, aluminium sealing crimps and polypropylene caps.

Holder of the certificate of registration

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