

Patient Information Leaflet

Chlorhexidine Gluconate 1% w/w (incorporated as
Chlorhexidine Gluconate Solution Ph.Eur 5% v/w)

HibitaneTM Obstetric Cream

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to you doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Hibitane Obstetric cream is and what it is used for
2. What you need to know before you use Hibitane Obstetric cream
3. How to use Hibitane Obstetric cream
4. Possible side effects
5. How to store Hibitane Obstetric cream
6. Contents of the pack and other information

1. WHAT HIBITANE OBSTETRIC CREAM IS AND WHAT IT IS USED FOR

Hibitane Obstetric cream contains a chemical called chlorhexidine gluconate which destroys germs. It is used as an antiseptic cream and lubricant by health care professionals when examining women during pregnancy or for gynaecological problems.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HIBITANE OBSTETRIC CREAM

Do not use Hibitane Obstetric cream:

- If you know you are sensitive or allergic to any of the ingredients (see section 6).

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Hibitane Obstetric cream.

- Take care to avoid application to the ears and eyes, and any deep cuts involving the head or spine. Wash out with water if necessary.
- If Hibitane Obstetric cream comes into contact with fabrics and bleach is used to remove it, brown stains may develop.
- If mixed with soap or detergents its effectiveness may be reduced.

Other medicines and Hibitane Obstetric cream

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

Pregnancy and breast-feeding

Hibitane Obstetric cream may be used during pregnancy and breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine when you are pregnant, think you may be pregnant, are planning to become pregnant, or are breast-feeding.

Driving and using machines

Hibitane Obstetric cream should not affect your ability to drive or use machinery.

Hibitane Obstetric cream contains cetostearyl alcohol

The ingredient cetostearyl alcohol may cause local skin reactions (eg. contact dermatitis) which can cause an itchy rash.

3. HOW TO USE HIBITANE OBSTETRIC CREAM

Hibitane Obstetric cream is used by health care professionals during a physical examination. Some will be spread onto the gloved hand of the examiner and some will be applied around your birth canal and anus.

Hibitane Obstetric cream is for use on the skin or vagina only.

If you have any further questions on the use of this medicine ask your doctor, pharmacist or nurse.

What to do if you accidentally swallow Hibitane Obstetric cream

If you accidentally swallow the cream, contact your doctor or nearest hospital.

4. POSSIBLE SIDE EFFECTS

Like all medicines Hibitane Obstetric cream can sometimes cause side effects, although not everybody has them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty breathing, swelling of the eyelids face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

The following side effects have been reported but how often they occur is not known:

You may notice some irritation of the skin or allergic (itchy) reaction when it is first applied.

If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HIBITANE OBSTETRIC CREAM

Keep this medicine out of the sight and reach of children.

This section is primarily for healthcare professionals. Do not use after the expiry date stated on the bottle. The expiry date refers to the last day of that month.

Keep at room temperature below 30°C.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hibitane Obstetric cream contains

The active ingredient is Chlorhexidine gluconate 1% w/w.

The other ingredients are cetostearyl alcohol, cetostearyl alcohol/ethylene oxide condensate, isopropyl alcohol, linally acetate, liquid paraffin, white soft paraffin and water.

What Hibitane Obstetric cream looks like and contents of pack

Hibitane Obstetric cream is a white thin cream available in 50ml, 10 x 50ml or 250ml bottles. Not all pack sizes may be marketed.

Marketing authorisation holder

Derma UK Ltd, The Toffee Factory, Lower Steenberg's Yard, Ouseburn, Newcastle upon Tyne NE1 2DF, UK.

Manufacturer

Laleham Health & Beauty Ltd, Fairfield, Bradshaw Lane, Preston, Lancashire PR4 3JA, UK.

This leaflet was last revised in March 2021.

Patient Information Leaflet

Chlorhexidine Gluconate 1% w/w (incorporated as
Chlorhexidine Gluconate Solution Ph.Eur 5% v/w)

HibitaneTM Obstetric Cream

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to you doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Hibitane Obstetric cream is and what it is used for
2. What you need to know before you use Hibitane Obstetric cream
3. How to use Hibitane Obstetric cream
4. Possible side effects
5. How to store Hibitane Obstetric cream
6. Contents of the pack and other information

1. WHAT HIBITANE OBSTETRIC CREAM IS AND WHAT IT IS USED FOR

Hibitane Obstetric cream contains a chemical called chlorhexidine gluconate which destroys germs. It is used as an antiseptic cream and lubricant by health care professionals when examining women during pregnancy or for gynaecological problems.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HIBITANE OBSTETRIC CREAM

Do not use Hibitane Obstetric cream:

- If you know you are sensitive or allergic to any of the ingredients (see section 6).

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Hibitane Obstetric cream.

- Take care to avoid application to the ears and eyes, and any deep cuts involving the head or spine. Wash out with water if necessary.
- If Hibitane Obstetric cream comes into contact with fabrics and bleach is used to remove it, brown stains may develop.
- If mixed with soap or detergents its effectiveness may be reduced.

Other medicines and Hibitane Obstetric cream

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

Pregnancy and breast-feeding

Hibitane Obstetric cream may be used during pregnancy and breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine when you are pregnant, think you may be pregnant, are planning to become pregnant, or are breast-feeding.

Driving and using machines

Hibitane Obstetric cream should not affect your ability to drive or use machinery.

Hibitane Obstetric cream contains cetostearyl alcohol

The ingredient cetostearyl alcohol may cause local skin reactions (eg. contact dermatitis) which can cause an itchy rash.

3. HOW TO USE HIBITANE OBSTETRIC CREAM

Hibitane Obstetric cream is used by health care professionals during a physical examination. Some will be spread onto the gloved hand of the examiner and some will be applied around your birth canal and anus.

Hibitane Obstetric cream is for use on the skin or vagina only.

If you have any further questions on the use of this medicine ask your doctor, pharmacist or nurse.

What to do if you accidentally swallow Hibitane Obstetric cream

If you accidentally swallow the cream, contact your doctor or nearest hospital.

4. POSSIBLE SIDE EFFECTS

Like all medicines Hibitane Obstetric cream can sometimes cause side effects, although not everybody has them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty breathing, swelling of the eyelids face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

The following side effects have been reported but how often they occur is not known:

You may notice some irritation of the skin or allergic (itchy) reaction when it is first applied.

If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HIBITANE OBSTETRIC CREAM

Keep this medicine out of the sight and reach of children.

This section is primarily for healthcare professionals. Do not use after the expiry date stated on the bottle. The expiry date refers to the last day of that month.

Keep at room temperature below 30°C.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hibitane Obstetric cream contains

The active ingredient is Chlorhexidine gluconate 1% w/w.

The other ingredients are cetostearyl alcohol, cetostearyl alcohol/ethylene oxide condensate, isopropyl alcohol, linalyl acetate, liquid paraffin, white soft paraffin and water.

What Hibitane Obstetric cream looks like and contents of pack

Hibitane Obstetric cream is a white thin cream available in 50ml, 10 x 50ml or 250ml bottles. Not all pack sizes may be marketed.

Marketing authorisation holder

Derma UK Ltd, The Toffee Factory, Lower Steenberg's Yard, Ouseburn, Newcastle upon Tyne NE1 2DF, UK

Manufacturer

Bioglan AB, PO Box 50310, S-202 13 Malmö, Sweden.

This leaflet was last revised in March 2021.