

Package Leaflet: Information for the user

Cetrimide 0.3% w/w
Dimeticone 1000 10% w/w

Siopel[®] Cream

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT SIOPEL CREAM IS AND WHAT IT IS USED FOR

Siopel cream contains two active ingredients, cetrimide and dimeticone. Cetrimide is an antiseptic which destroys germs. Dimeticone protects the skin from water.

Siopel cream is used as a water repellent barrier cream with antiseptic properties. It is useful when the skin needs to be protected from water or external irritants.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SIOPEL CREAM

Do not use Siopel cream:

- If you are allergic to cetrimide or dimeticone or any of the other ingredients of this medicine (listed in section 6). [Please note: Siopel cream contains Arachis oil (peanut oil) **and should not be applied by patients known to be allergic to peanut**. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Siopel cream.]
- In body cavities or as an enema
- On skin that is acutely inflamed (i.e. red and angry) or weeping
- Before the skin has been cleansed of any irritants

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Siopel 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 mixed with soap or detergents its effectiveness may be reduced

Other medicines and Siopel 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

Siopel 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

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

Siopel cream contains Arachis oil (peanut oil), cetostearyl alcohol and methyl-parahydroxybenzoate.

Siopel cream contains Arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Siopel cream.

The ingredient cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) which can cause an itchy rash. Methyl-parahydroxybenzoate may cause local skin reactions (possibly delayed).

3. HOW TO USE SIOPEL CREAM

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Siopel cream is for external use only. Wash and dry the skin first. Then apply the cream sparingly and massage well into the skin.

For the first 3-4 days: apply three to five times daily. *After that:* apply once or twice daily.

What to do if you accidentally swallow Siopel cream

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

If you forget to use Siopel cream

If you forget to apply a dose, do so as soon as you remember and then go on as before.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Siopel cream can sometimes cause side effects, although not everybody gets them.

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 after repeated applications.

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 at 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 SIOPEL CREAM

Keep out of the sight and reach of children. Your medicine could harm them.

Do not use this medicine after the expiry date stated on the tube and carton. The expiry date refers to the last day of that month.

Store below 25°C, in a dry place.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Siopel cream contains

The active substances are cetrимide 0.3% w/w and dimeticone 1000 10% w/w.

The other ingredients are arachis oil, butylated hydroxytoluene, cetostearyl alcohol, anhydrous citric acid, methyl-parahydroxybenzoate and purified water.

See section 2 'Do not use' and 'Important information about some of the ingredients' for advice on Arachis oil (peanut oil), cetostearyl alcohol and methyl-parahydroxybenzoate.

What Siopel cream looks like and contents of pack

Siopel cream is a white cream available in tubes of 50 grams.

Marketing authorisation holder


Derma UK Ltd, The Toffee Factory, Lower Steenbergs 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 May 2017.

XXXXXX

CLIENT	Derma UK	SIZE mm	208 x 147	PROOF	22/12/11, 12/1/12, 3/7/12,
	Siopel Cream PIL	MOD	3396da Siopel cr pilD&B		14/1/15, 19/8/15, 27/11/15,
BRIEF	JI 16/12/11	PROGS	QuarkXpress 6.5		16/12/15, 12/5/17
PHARMA CODE	-	FONTS	Helvetica Neue 45, 55, 85	COLOURS, PMS	
COMPONENT	-		(ITC BT Franklin Bk, Med, Demi)		
BAR CODE	-				 Black

Package Leaflet: Information for the user

Cetrimide 0.3% w/w
Dimeticone 1000 10% w/w

Siopel[®] Cream

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT SIOPEL CREAM IS AND WHAT IT IS USED FOR

Siopel cream contains two active ingredients, cetrimide and dimeticone. Cetrimide is an antiseptic which destroys germs. Dimeticone protects the skin from water.

Siopel cream is used as a water repellent barrier cream with antiseptic properties. It is useful when the skin needs to be protected from water or external irritants.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SIOPEL CREAM

Do not use Siopel cream:

- If you are allergic to cetrimide or dimeticone or any of the other ingredients of this medicine (listed in section 6). [Please note: Siopel cream contains Arachis oil (peanut oil) **and should not be applied by patients known to be allergic to peanut**. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Siopel cream.]
- In body cavities or as an enema
- On skin that is acutely inflamed (i.e. red and angry) or weeping
- Before the skin has been cleansed of any irritants

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Siopel 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 mixed with soap or detergents its effectiveness may be reduced

Other medicines and Siopel 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

Siopel 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

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

Siopel cream contains Arachis oil (peanut oil), cetostearyl alcohol and methyl-parahydroxybenzoate.

Siopel cream contains Arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Siopel cream.

The ingredient cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) which can cause an itchy rash. Methyl-parahydroxybenzoate may cause local skin reactions (possibly delayed).

3. HOW TO USE SIOPEL CREAM

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Siopel cream is for external use only. Wash and dry the skin first. Then apply the cream sparingly and massage well into the skin.

For the first 3-4 days: apply three to five times daily. *After that:* apply once or twice daily.

What to do if you accidentally swallow Siopel cream

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

If you forget to use Siopel cream

If you forget to apply a dose, do so as soon as you remember and then go on as before.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Siopel cream can sometimes cause side effects, although not everybody gets them.

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 after repeated applications.

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 at 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 SIOPEL CREAM

Keep out of the sight and reach of children. Your medicine could harm them.

Do not use this medicine after the expiry date stated on the tube and carton. The expiry date refers to the last day of that month.

Store below 25°C, in a dry place.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Siopel cream contains

The active substances are cetrимide 0.3% w/w and dimeticone 1000 10% w/w.

The other ingredients are arachis oil, butylated hydroxytoluene, cetostearyl alcohol, anhydrous citric acid, methyl-parahydroxybenzoate and purified water.

See section 2 'Do not use' and 'Important information about some of the ingredients' for advice on Arachis oil (peanut oil), cetostearyl alcohol and methyl-parahydroxybenzoate.

What Siopel cream looks like and contents of pack

Siopel cream is a white cream available in tubes of 50 grams.

Marketing authorisation holder


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

Manufacturer

Pharmasol Ltd, Walworth Industrial Estate, Andover, Hants SP10 5AZ.

This leaflet was last revised in May 2017.

XXXXXX

CLIENT	Derma UK	SIZE mm	208 x 147	PROOF (ex D&B 12/5/17)	12/5/17
	Siopel Cream PIL	MOD	3396da Siopel cr pilD&B		
BRIEF	JI 16/12/11	PROGS	QuarkXpress 6.5		
PHARMA CODE	-	FONTS	Helvetica Neue 45, 55, 85 (ITC BT Franklin Bk, Med, Demi)	COLOURS, PMS	
COMPONENT	-				Black
BAR CODE	-				