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Consumer Medication Information Leaflet (RiMUP)

# BETADINE® ANTISEPTIC OINTMENT

Povidone-Iodine (10%w/w)

## What is in this leaflet

1. What **BETADINE®** Antiseptic Ointment is used for
2. How **BETADINE®** Antiseptic Ointment works
3. Before you use **BETADINE®** Antiseptic Ointment
4. How to use **BETADINE®** Antiseptic Ointment
5. While you are using it
6. Side effects
7. Storage and Disposal of **BETADINE®** Antiseptic Ointment
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What **BETADINE®** Antiseptic Ointment is used for

- Cuts and bruises
- Burns
- Bacterial and Mycotic (fungal) skin infections eg. at groins, feet
- Cold sores
- Viral infection such as Herpes simplex, Herpes genitalis
- Disinfection of skin for catheterization procedure

## How **BETADINE®** Antiseptic Ointment works

**BETADINE®** Antiseptic Ointment contains a medicine called Povidone-Iodine that kills bacteria, viruses, fungi, spores and protozoa.

## Before you use **BETADINE®** Antiseptic Ointment

- **When you must not use it**
- If you are allergic to iodine or Povidone or other ingredients in this product;
- If you have thyroid disease.

## Pregnancy and lactation

Always inform your doctor or pharmacist if you are pregnant or planning a pregnancy, before using **BETADINE®** Antiseptic Ointment.

This medicine should not be used during pregnancy unless there is no alternative treatment available.

Seek medical advice from your doctor or pharmacist.

## Before you start use it

Tell your doctor or pharmacist if you: have other illness or health conditions

## Taking other medicines

Absorption of iodine from povidone iodine through either intact skin or broken skin may interfere with thyroid function tests.

Do not apply other medications to the same affected areas you treat with

**BETADINE®** Antiseptic Ointment, unless your doctor has told you so.

Do not start a new treatment medication without telling your doctor.

For more information about any other possible risks associated with this medicine, please consult your doctor or pharmacist.

## How to use **BETADINE®** Antiseptic Ointment

**- How much to use it**  
Clean and dry affected skin. Apply to the affected area and sterile dressing may be applied after application.

**BETADINE®** Antiseptic Ointment may be used as often as required.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

## When to use it

Use as directed by your doctor or pharmacist.

## How long to use it

Continue taking **BETADINE®** Antiseptic Ointment for as long as your doctor or pharmacist recommends.

## If you forget to use it

Use immediately as soon as you remember. If it is almost time for the next dose, skip the dose missed and apply only the next regular scheduled dose as instructed.

## If you use too much (overdose)

Application to large areas of broken skin should be avoided as excessive absorption of iodine may occur.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## While you are using it

### Things you must do

Use **BETADINE®** Antiseptic Ointment exactly as your doctor or pharmacist has told you.

If redness, irritation, swelling or pain persist or increases or infection occurs, discontinue use and consult a doctor.

Tell all the doctors and pharmacists treating you that you are using **BETADINE®** Antiseptic Ointment.

Tell your doctor immediately if you become pregnant while using this Antiseptic Ointment.

## Things you must not do

Avoid getting this medicine in your eyes.

## Things to be careful of

**BETADINE®** Antiseptic Ointment is intended FOR EXTERNAL USE ONLY.

Use of this preparation may interfere with tests of thyroid function. If symptoms occur suggesting changes in thyroid function, these should be investigated.

## Side effects

Like all medicines, **BETADINE®** Antiseptic Ointment can cause side effects, although not everybody gets them.

If allergic reactions which can appear in the form of itching, redness and small blister develop, discontinue treatment.

Visit your doctor or pharmacist immediately if you experience any side effects after using.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of **BETADINE®** Antiseptic Ointment

**- Storage**  
Store below 30°C.

Keep out of the reach of children.

## Disposal

If the product exceeds expiry date, talk to your doctor or pharmacist about the proper disposal.

## Product Description

### What it looks like

**BETADINE®** Antiseptic Ointment is a brown homogenous ointment soluble in water.

## Packing

**BETADINE®** Antiseptic Ointment is available in a printed aluminium tube which enclosed in printed carton.

## Ingredients:

- Active ingredient  
Povidone-Iodine 10% w/w
- Inactive ingredient  
Macrogol 4000  
Sodium Bicarbonate  
Macrogol 400  
Purified Water

## MAL Number:

MAL19910202XCZ

## Manufacturer

Mundipharma Pharmaceuticals Ltd  
13-15 Othellos Street, Dhali Industrial Area, Nicosia, Cyprus, 2540, Cyprus.

## Product Registration Holder

iNova Pharmaceuticals (Singapore) Pte. Ltd.  
(Incorporated in Singapore) Malaysia Branch  
5F-2, 5th Floor, Tower 2, @PFCC, Jalan Puteri 1/2, Bandar Puteri, 47100 Puchong, Selangor, Malaysia.

## Date of revision

8/4/2025

## Serial Number

NPRA(R2/1)221114/976

A10811



2D Code : 10223402  
Size : 5x5 mm.  
2D Code area : 7x7 mm.  
Clear area : 1 mm.

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Risalah Maklumat Ubat untuk Pengguna (RiMUP)

# BETADINE® ANTISEPTIC OINTMENT

Povidone-Iodine (10%w/w)

## Apakah yang ada pada risalah ini

1. Apakah kegunaan **BETADINE®** Antiseptic Ointment
2. Bagaimana **BETADINE®** Antiseptic Ointment berfungsi
3. Sebelum menggunakan **BETADINE®** Antiseptic Ointment
4. Cara menggunakan **BETADINE®** Antiseptic Ointment
5. Semasa menggunakan **BETADINE®** Antiseptic Ointment
6. Kesan-kesan sampingan
7. Cara penyimpanan dan pelupusan **BETADINE®** Antiseptic Ointment
8. Maklumat lanjut
9. Pengilang dan Pemegang Pendaftaran Produk
10. Tarikh kemaskini RiMUP

## Apakah kegunaan **BETADINE®** Antiseptic Ointment

- Luka dan lebam
- Luka terbakar
- Jangkitan kulit bakteria dan mikosis (kulat) seperti di celah paha, kaki
- Lepuh sejuk
- Jangkitan virus seperti Herpes simpleks, Herpes genitalis
- Pembasmian kuman kulit untuk prosedur katerisasi

## Bagaimana **BETADINE®** Antiseptic Ointment berfungsi

**BETADINE®** Antiseptic Ointment mengandungi sejenis ubat yang dipanggil Povidone-Iodine yang boleh membunuh bakteria, virus, kulat, spora dan protozoa.

## Sebelum menggunakan **BETADINE®** Antiseptic Ointment

- **Bila tidak boleh menggunakannya**
- Jika anda alah terhadap iodine atau povidone atau bahan lain dalam produk ini;
- Jika anda ada penyakit tiroid.

## Mengandung dan menyusukan anak

Sebelum menggunakan **BETADINE®** Antiseptic Ointment, beritahu doktor atau ahli farmasi jika anda hamil atau bercadang untuk hamil.

Ubat ini tidak boleh digunakan semasa mengandung melainkan jika tiada rawatan alternatif.

Dapatkan nasihat daripada doktor atau ahli farmasi.

## Sebelum menggunakan **BETADINE®** Antiseptic Ointment

Beritahu doktor atau ahli farmasi jika anda: mempunyai masalah kesihatan atau penyakit lain.

## Jika mengambil ubat-ubat lain

Penyerapan iodine daripada povidone-Iodine sama ada melalui kulit sihat atau kulit yang luka mungkin mengganggu ujian fungsi tiroid.

Jangan sapu ubat lain pada kawasan yang sama jika anda sedang dirawat dengan **BETADINE®** Antiseptic Ointment, melainkan atas arahan doktor.

Jangan mulakan rawatan dengan ubat yang baru tanpa memberitahu doktor anda.

Untuk mendapatkan maklumat selanjutnya mengenai risiko lain yang boleh timbul kerana menggunakan ubat ini, tanyalah doktor atau ahli farmasi.

## Cara menggunakan **BETADINE®** Antiseptic Ointment

**- Berapa banyak harus digunakan**  
Bersihkan dan keringkan bahagian terjejas. Sapukan salap pada bahagian terjejas dan balut dengan pembalut kain steril jika perlu. **BETADINE®** Antiseptic Ointment boleh disapu sekerap yang diperlukan.

Jika anda tidak memahami arahan pada label, tanya doktor atau ahli farmasi.

## Bila perlu digunakan

Ikut arahan doktor atau ahli farmasi.

## Berapa lama perlu digunakan

Teruskan penggunaan **BETADINE®** Antiseptic Ointment untuk tempoh masa yang ditetapkan oleh doktor atau ahli farmasi anda.

## Jika terlupa menggunakan

Ambil dos yang terlepas sebaik sahaja anda teringat. Jika sudah hampir masa untuk dos seterusnya, abaikan dos yang tertinggal dan guna pada dos seterusnya seperti yang diarahkan.

## Jika mengguna berlebihan (terlebih dos)

Penggunaan pada kawasan kulit luka yang besar harus dielakkan kerana penyerapan iodine yang berlebihan boleh berlaku. Hubungi doktor dengan segera atau pergi ke Jabatan Kecemasan hospital berhampiran, jika anda rasa anda atau orang lain mungkin telah menggunakan ubat ini terlalu banyak. Lakukannya walaupun tiada tanda tidak selesa atau terkena racun. Anda mungkin perlu rawatan perubatan segera.

## Semasa menggunakan **BETADINE®** Antiseptic Ointment

### Perkara yang perlu dilakukan

Gunakan **BETADINE®** Antiseptic Ointment anda mengikut arahan doktor atau ahli farmasi.

Jika kemerahan, kerengsaan, bengkak atau sakit terus berlanjutan atau bertambah atau jangkitan berlaku, hentikan penggunaan dan rujuk kepada doktor.

Maklumkan kepada semua doktor dan ahli farmasi yang merawat anda bahawa anda sedang menggunakan **BETADINE®** Antiseptic Ointment.

Beritahu doktor anda dengan segera jika anda hamil semasa menggunakan ubat ini.

## Perkara yang tidak boleh dilakukan

Elakkan ubat ini daripada terkena mata.

## Perkara yang perlu diberi perhatian

**BETADINE®** Antiseptic Ointment adalah UNTUK KEGUNAAN LUAR SAHAJA.

Penggunaan produk ini boleh mengganggu ujian fungsi tiroid. Jika simptom yang mengganggu fungsi tiroid dikesan, ini seharusnya disiasat.

## Kesan-kesan sampingan

Seperti ubat-ubatan lain **BETADINE®** Antiseptic Ointment boleh menyebabkan kesan sampingan, walaupun bukan semua orang mengalaminya.

Jika berlaku alahan yang dikesan seperti gatal-gatal, kemerahan dan lepuh kecil, berhenti menggunakannya.

Jumpa doktor atau ahli farmasi dengan segera jika anda mengalami sebarang kesan sampingan selepas menggunakan ubat ini.

Anda boleh melaporkan sebarang kesan sampingan atau kesan adwers ubat kepada Pusat Pemantauan Kesan Adwers Ubat Kebangsaan melalui laman web npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Cara penyimpanan dan pelupusan **BETADINE®** Antiseptic Ointment

### Penyimpanan

Simpan di bawah suhu 30°C.

Jauhi daripada kanak-kanak

### Pelupusan

Sekiranya produk melebihi tarikh luput, berbincang dengan doktor atau ahli farmasi mengenai cara pelupusan.

## Maklumat lanjut

### Rupa dan warna produk

**BETADINE®** Antiseptic Ointment adalah salap berwarna coklat sekata yang boleh larut dalam air.

### Pembungkusan

**BETADINE®** Antiseptic Ointment boleh didapati dalam tiub aluminium bercetak yang disertakan dalam kotak bercetak.

### Bahan-bahan kandungan

- Bahan aktif  
Povidone-Iodine 10% w/w
- Bahan bukan aktif  
Macrogol 4000  
Sodium Bicarbonate  
Macrogol 400  
Purified Water

### Nombor MAL

MAL19910202XCZ

## Pengilang

Mundipharma Pharmaceuticals Ltd  
13-15 Othellos Street, Dhali Industrial Area, Nicosia, Cyprus, 2540, Cyprus.

## Pemegang Pendaftaran Produk

iNova Pharmaceuticals (Singapore) Pte Ltd (Incorporated in Singapore)  
Malaysia Branch 5F-2, 5th Floor, Tower 2, @ PFCC, Jalan Puteri 1/2, Bandar Puteri, 47100 Puchong, Selangor, Malaysia.

## Tarikh kemaskini RiMUP

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## Nombor siri

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<b>A10811_BETADINE 10% OINTMENT 20G</b> <b>Component : LEAFLET</b> <b>Country : MY</b>	<b>G247 File Name:</b> 109543_A10811_BETADINE 10% OINTMENT 20G_MY_LT_V1	<b>Dieline Ref:</b> PP-6858 <b>EMO:</b> MUNDIPHARMA (CYPRUS) <b>Printer:</b> Irida	

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Povidone-Iodine (10%w/w) 2.50 mm. 10.00 pt Times New Roman Regular

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