



KEMENTERIAN KESIHATAN MALAYSIA
(Ministry of Health Malaysia)
Bahagian Regulatori Farmasi Negara (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya
Selangor
MALAYSIA

No. Telefon : 03 - 7883 5400
No. Faksimili : 03 - 7956 2924
Portal Rasmi : <http://npa.moh.gov.my>
E-mel Rasmi : npa@npa.gov.my

Ruj.Kami : (10) dlm.BPFK/PASCA/FV/15/Jilid 36
Tarikh : **31 MAY 2019**

UNIMED SDN. BHD.
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200, Kuala Lumpur
(u/p: Ms. Shalini, Regulatory Affairs)

Puan,

RISALAH MAKLUMAT UBAT UNTUK PENGGUNA (RiMUP)

Nama Produk

METROGYL SUSPENSION

- **DIDANOSINE ENTERIC COATED DELAYED RELEASE CAPSULES 250MG**
- **DIDANOSINE ENTERIC COATED DELAYED RELEASE CAPSULES 400MG**

Nombor Pendaftaran

MAL19872154AZ

MAL11040007AZ

MAL11040008AZ



Saya merujuk kepada perkara di atas dan maklumbalas terkini puan bertarikh 31 Mei 2019 dan 29 Apr 2019 adalah berkaitan.

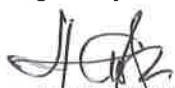
2. Semakan telah dibuat terhadap draf Risalah Maklumat Ubat Untuk Pengguna (RiMUP) dan mendapati risalah ini mematuhi garispanduan yang ditetapkan serta boleh digunakan.

3. Pemegang pendaftaran produk adalah diingatkan bahawa permohonan variasi melalui sistem Quest 3+ masih perlu dilakukan untuk mendapatkan kelulusan sebelum implementasi Risalah Maklumat Ubat Untuk Pengguna (RiMUP) yang terkini dilaksanakan.

Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”

Saya yang menjalankan amanah,


(NORLEEN MOHAMED ALI)RPh4232

Ketua Seksyen Farmakovigilans

b.p. Timbalan Pengarah

Pusat Pasca Pendaftaran Produk & Kawalan Kosmetik

Bahagian Regulatori Farmasi Negara

Kementerian Kesihatan Malaysia

NMA/bvs

✉ norleen@npa.gov.my/bavahrni@npa.gov.my

☎ +603 - 78835492/ 78835499

☎ +603 - 79567151

s.k. Ketua Seksyen Ubat Generik, Pusat Pendaftaran Produk

METROGYL SUSPENSION

Consumer Medication Information Leaflet (RiMUP)

Benzoyl Metronidazole (200mg/ 5ml)

What is in this leaflet

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

What Metrogyl suspension is used for

Metrogyl suspension is used to treat certain infections caused by bacteria and other organisms in different parts of the body.

How Metrogyl suspension works

Metrogyl suspension is an antibiotic that belongs to a group of medicines called nitroimidazoles. This medicine works by killing or stopping the growth of bacteria and other organisms causing these infections.

Before you use Metrogyl suspension

- When you must not use it

Do not take Metrogyl suspension if:

- You have ever had an allergic reaction to Metronidazole or any other nitroimidazoles.

Pregnancy and lactation

Please consult your doctor before start to use Metrogyl suspension if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Metrogyl suspension against the benefits they expect it will have for you.

- Before you start to use it

You must tell your doctor if you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

Tell your doctor if you have or have ever had any health problems/ medical conditions including:

- Severe liver disease
- Disease of the brain, spinal cord or nerves

- Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Metrogyl suspension or may affect how well it works. These include:

- Alcohol
- Disulfiram, a medicine used to treat chronic alcohol dependence.
- Warfarin or other medicines used to prevent blood clots.
- Phenytoin, a drug used to treat convulsions.
- Lithium, a medicine used to treat manic depressive illness and some other types of depression.
- Phenobarbitone, a medicine for convulsions or sedation
- Cimetidine, a medicine used to treat gastric reflux and ulcers

How to use Metrogyl suspension

Always use Metrogyl suspension exactly as your doctor or pharmacist has told you.

- How much to use

For oral administration only.

Childrens:

35 to 50 mg/kg/24 hours, divided into three doses, orally for 10 days.

- When to use it

Your doctor will decide when it is appropriate to take Metrogyl suspension according to the type of condition you have.

- How long to use it

Consult with your doctor or pharmacist for the treatment period. Continue taking Metrogyl suspension for as long as your doctor recommends.

Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

- If you forget to use it

If you forget to use the Metrogyl suspension at the right time, use it as soon as you remember, then carry on as before.

Do not double the dose to catch up.

- If you use too much (overdose)

It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital if you did take Metrogyl suspension too much.

While you are using it

- Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Metrogyl suspension.

Take the Metrogyl suspension according to the recommended dosage.

- Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not take your medicine more than the suggested frequency in a day.

Things to be careful of

Discontinue use if irritation or sensitivity reaction develops.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Metrogyl suspension can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Strange metallic taste in mouth
- Furry tongue
- Inflamed and sore mouth
- Blood problems
- Heart problem
- Seizures
- Dizziness
- Poor coordination
- Confusion
- Irritability
- Depression
- Weakness
- Difficulty sleeping
- Nasal congestion
- Dry mouth, dryness of the mouth (or vagina or vulva)
- Fever
- Unusual urination patterns (e.g. difficulty in passing urine)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Metrogyl suspension**- Storage**

Store below 30°C in a cool place.

Protect from light.

- Disposal

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.

Product Description**- What it looks like**

Light orange coloured, viscous suspension having characteristics fruity flavour with sweet taste.

- Ingredients

- Active ingredient
Benzoyl Metronidazole

- Inactive ingredients

Colour Sunset Yellow FC, Essence Mix Fruit Inhouse, Guar B.P, Sucrose BP, Essence Peppermint Inhouse, Sodium propyl hydroxybenzoate, Sodium methyl hydroxybenzoate, Sorbitol solution 70%, Sorbic acid, Purified water BP and Polysorbate 80 BP.

- MAL number:

MAL19872154AZ

Manufacturer

Unique Pharmaceutical Laboratories
(A Division J. B.
Chemicals & Pharmaceuticals
Plot No. 215,216, G.I.D.C. Industrial
Area, Panoli: 394 116, Dist. Bharuch,
India.

Product Registration Holder

Unimed Sdn Bhd
53, Jalan Tembaga SD 5/2B, Bandar Sri
Damansara, 52200, Kuala
Lumpur, Malaysia.

Date of revision

24/10/2019

Serial Number:

NPRA(R4/1)280219/00067