

# 第 1 8 号

出典：添付文書 ZOLEROL 0.5% Infusion  
（メトロニダゾール 0.5% 静注など）  
南アフリカ添付文書トリコモナス症などの治療に使用

抗トリコモナス症

®ZOLEROL 200 mg TABLETS  
®ZOLEROL 400 mg TABLETS  
®ZOLEROL 0,5% INFUSION



SCHEDULING STATUS:  
S4

PROPRIETARY NAME  
(and dosage form):

- ®ZOLEROL 200 mg TABLETS
- ®ZOLEROL 400 mg TABLETS
- ®ZOLEROL 0,5% INFUSION

COMPOSITION:  
200 mg and 400 mg metronidazole per tablet with 0,1 % m/m methyl hydroxybenzoate as preservative.  
500 mg metronidazole per 100 mL i.v. infusion.

PHARMACOLOGICAL CLASSIFICATION:  
A. 20.2.6 (Medicines against Protozoa).

PHARMACOLOGICAL ACTION:  
Metronidazole has anti-protozoal activity and is effective against *Trichomonas vaginalis*, *Entamoeba histolytica* and *Giardia lamblia*. Metronidazole has bactericidal activity in vitro against several anaerobic organisms.

- INDICATIONS:
1. .Trichomonas infections in both males and females.
  2. .All forms of amoebiasis.
  3. .Lambliasis and Vincent's infection.
  4. .Treatment of infections in which anaerobic bacteria have been identified or are suspected as pathogens, particularly *Bacteroides fragilis* and other species of *Bacteroides* and including other species for which metronidazole is bactericidal.
  5. .Prevention of post-operative infections due to anaerobic bacteria.

CONTRA-INDICATIONS:  
Hypersensitivity to metronidazole.  
In patients with blood dyscrasias or with active disease of the central nervous system.  
Its use should be avoided during pregnancy.

WARNINGS:  
Pseudomembranous colitis has been reported with the use of metronidazole.

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**DOSAGE AND DIRECTIONS FOR USE:**

Tablets should be swallowed with half a glassful of water during or after meals. Seven days treatment should be satisfactory for most patients. Prolonged treatment can be used if the physician considers it to be necessary.

Immature children and babies with a bodymass less than 12 kg should receive proportionately smaller dosage as advised by the physician.

Children over 10 years may be given a suitable proportion of the adult dosage according to bodymass.

**1. Treatment of Anaerobic Infections.**

Adults and children over 12 years:

400 mg three times daily.

Children under 12 years:

7,5 mg/kg body mass three times daily.

**2. Prevention of Anaerobic Infections:**

Gynaecological Surgery.

Adults:

2 g as a single dose followed by 200 mg three times daily until pre-operative withholding of solids and liquids by mouth becomes necessary. Medication with 200 mg three times daily should be resumed after the operation and continued for up to seven days.

**3. Vincent's Infection:**

Adults and children over 12 years:

200 mg three times daily for three days or 400 mg orally morning and evening for three days.

**4. Treatment of Trichomonas Infections:**

(To prevent re-infection the consort should receive a similar course of treatment concurrently).

Adults and children over 12 years:

either, 200 mg three times daily for seven days, or, 800 mg morning and 1,2 g evening for two days.

**5. Treatment of Amoebic Infections:**

Adults and children over 12 years:

800 mg three times daily for 5-10 days.

**6. Treatment of Lambliasis:**

Adults and children over 12 years:

2 g once daily for three days.

In severe infections metronidazole may be given intravenously -100 mL of a 0,5% solution is given at a rate of 5 mL per minute every 8 hours, with oral administration substituted as soon as possible. A similar parenteral dose has been used for prophylaxis. For children each intravenous dose contains 7,5 mg per kg.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Side-effects include gastro-intestinal discomfort, anorexia, nausea, coated tongue, dry mouth and unpleasant taste, headache pruritus, and skin rash. Other side-effects are vomiting, diarrhoea, weakness, vertigo, ataxia, depression, insomnia, drowsiness, urethral discomfort and darkening of the urine. There may be temporary leucopenia, and bone marrow depression. Peripheral neuropathy has been reported in patients on prolonged therapy. Alcohol should be avoided during treatment as metronidazole may provoke a disulfiram-like reaction. Metronidazole enhances the anticoagulant effect of warfarin.

Slight and transient falls in blood pressure have been reported. It may therefore be advisable to lower the dosages of any antihypertensive drug which may be given concurrently with ZOLEROL.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

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See side-effects.

In recent overdosage gastric lavage is recommended.

Further treatment is symptomatic and supportive.

**IDENTIFICATION:**

400 mg tablets: Yellow biconvex tablet scored on one side.

200 mg tablets: White biconvex tablet scored on one side.

100 mL infusion: Clear, colourless or slightly yellow aqueous solution.

**PRESENTATION:**

Containers with 10, 21, 100, 250, 500 and 1000 tablets.

100 mL clear colourless bottles containing a 0,5% intravenous solution.

**STORAGE INSTRUCTIONS:**

Keep in a dry place below 25° C.

Protect from light.

Keep out of reach of children.

**REGISTRATION NUMBER:**

200 mg: S/20.2.6/230

400 mg: S/20.2.6/153

0,5 % infusion: W/20.2.6/175

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

ROLAB (PTY) LTD

65 Maria Street

Fontainebleau

Randburg

2194

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

6 June 1990

® Registered Trade Mark

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