

**TAGERA FORTE
(Secnidazole Tablets 1 g)**

Unichem Laboratories Limited

1.3 Product Information

1.3.1 Summary of product characteristics (SmPC)

Summary of products characteristics (SmPC) of TAGERA FORTE (Secnidazole Tablets 1 g) is enclosed overleaf.

SUMMARY OF PRODUCTS CHARACTERISTICS

TAGERA FORTE (Secnidazole Tablets 1 g)

1. Name of the Medicinal Product

1.1 Product name : TAGERA FORTE

1.2 Strength : Secnidazole 1 g Tablets

1.3 Pharmaceutical Dosage form : Tablets

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration : The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.

Refer Standard Batch Formula enclosed overleaf.

2.2 Quantitative Declaration : The quantity of the active substance must be expressed per dosage unit (for metered dose inhalation products, per puff) per unit volume or per unit of weight).

Refer Standard Batch Formula enclosed overleaf.

Sr. No.	Ingredients	Quantity /mg	Function
Dry Mix			
1	Secnidazole O. Sp.	1000.000	Active
2	Microcrystalline Cellulose Ph. Eur./BP	100.000	Diluent
Binder			
3	Maize Starch Ph. Eur./BP	45.000	Binder
4	Gelatin Ph. Eur./BP	5.000	Binder
5	**Purified Water Ph. Eur./BP /USP/IP	q.s.	Solvent
Pre-lubrication			
6	Sodium Starch Glycolate (Type A) Ph. Eur./BP	50.000	Disintegrant
7	Colloidal Anhydrous Silica Ph. Eur./BP	20.000	Glidant
Lubrication			
8	Magnesium Stearate Ph. Eur./BP	30.000	Lubricant
	Total Theoretical Weight	1250.000	—
Film coating			
9	Hydroxypropyl methylcellulose 5 cps Ph. Eur./BP	15.000	Film Former
10	Macrogol Ph. Eur./BP	3.000	Plasticizer
11	Titanium Dioxide USP/NF	7.000	Colouring Agent
12	** Dichloromethane Ph. Eur./BP	q.s.	Coating Solvent
13	** Ethanol Ph. Eur./BP	q.s.	Coating Solvent
	Total Weight of Coated Tablet	1275.00	—

** -Evaporates during drying and does not appear in final product.

SUMMARY OF PRODUCTS CHARACTERISTICS

TAGERA FORTE (Secnidazole Tablets 1 g)

3. Pharmaceutical Form

Tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication(s)

Secnidazole is indicated for the treatment of intestinal and extra intestinal amoebiasis, trichomoniasis, giardiasis and bacterial vaginosis.

4.2 Posology and method of administration

Adult :

Intestinal amoebiasis – 2 g single dose

Amoebic liver abscess - 1.5 g per day for 5 days

Trichomoniasis and bacterial vaginosis for patient and partner – 2 g single dose

Giardiasis – 2 g single dose

Children :

Intestinal amoebiasis and giardiasis - 30 mg / kg body weight as single or divided doses.

4.3 Contra-indications

As in the case of all imidazole derivatives, Secnidazole should not be administered during the first trimester of pregnancy or during lactation or in individuals having hypersensitivity to imidazole derivatives. Avoid alcohol and disulfiram during treatment. Avoid use in patients with past history of blood disorders.

4.4 Special warnings and precautions for use

As in the case of all imidazole derivatives, Secnidazole should not be administered during the first trimester of pregnancy or during lactation or in individuals having hypersensitivity to imidazole derivatives. Avoid alcohol and disulfiram during treatment. Avoid use in patients with past history of blood disorders.

4.5 Interaction with other medicinal products and other forms of interaction

Secnidazole may potentiate the anticoagulant effect of warfarin thereby increasing the risk of haemorrhage. Alcoholic beverages should be avoided during the secnidazole therapy and at least one day afterwards because antabuse effect may occur. Similarly consumption of secnidazole with disulfiram should not be allowed in order to avoid occurrence of delirious bouts and confusion.

4.6 Fertility, pregnancy and lactation

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4.7 Effects on the ability to drive and use machines

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SUMMARY OF PRODUCTS CHARACTERISTICS

TAGERA FORTE (Secnidazole Tablets 1 g)

4.8 Undesirable effects

Secnidazole is well tolerated. Majority of side effects are of mild and transient nature. They include nausea, vomiting, gastralgia, metallic taste, glossitis, stomatitis and urticaria. Vertigo, dizziness, headache and neurological disturbances occur very rarely.

4.9 Overdose

To the best of our knowledge, no instances of deliberate or accidental overdose with Secnidazole have been reported so far. In the event of overdosage, supportive and symptomatic therapy is indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Secnidazole is an orally active 5-Nitroimidazole with long half-life.

5.2 Pharmacokinetic properties

Secnidazole is rapidly and completely absorbed after oral administration. Following oral administration of Secnidazole, the maximum serum level is obtained after 3 hours. Plasma drug concentration are linear over the therapeutic dose range of 0.5 to 2 grams. The plasma elimination half life time is about 20-25 hours. Secnidazole crosses the placental barrier and can be found in maternal milk. Most of the absorbed drug is excreted via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Maize Starch
Gelatin
Sodium starch Glycollate
Colloidal silicon dioxide
Magnesium stearate
Hydroxypropyl methylcellulose
Polyethylene glycol
Titanium dioxide
Ethanol
Methylene chloride

6.2 Incompatibilities

None known

6.3 Shelf-life

36 months

SUMMARY OF PRODUCTS CHARACTERISTICS

TAGERA FORTE (Secnidazole Tablets 1 g)

6.4 Special precautions for storage

Store below 30° C. Protect from light and moisture. Keep all medicines out of reach of children.

6.5 Nature and contents of container

A transparent blister of PVC with a printed aluminium foil as lidding is the container. 2 Tablets are packed in this blister. Blisters & Leaflet in turn are packed in a carton/s.

6.6 Special precautions for disposal < and other handling >

No special requirements.

7. Marketing authorization holder and manufacturing site addresses

Corporate Office:

Unichem Laboratories Limited,
Unichem Bhavan, Prabhat Estate,
S. V. Road, Jogeshwari (West),
Mumbai – 400 102, INDIA
Phone: 91-22-66888333
Fax: 91-22-26785198/4391

Manufacturing Site:

Unichem Laboratories Limited,
C-31, C-32 and D-10, Industrial Area,
Meerut Road, Ghaziabad – 201003 Uttar Pradesh.
India
Phone: + 00-91-120-2750039, 2750040, 2750041
Fax: + 00-91-120-2750046

8. Marketing Authorization Number : A4-4663

9. Date of first authorization/renewal of the authorization : 6th December 2017

10. Date of revision of the text: Sep 2015

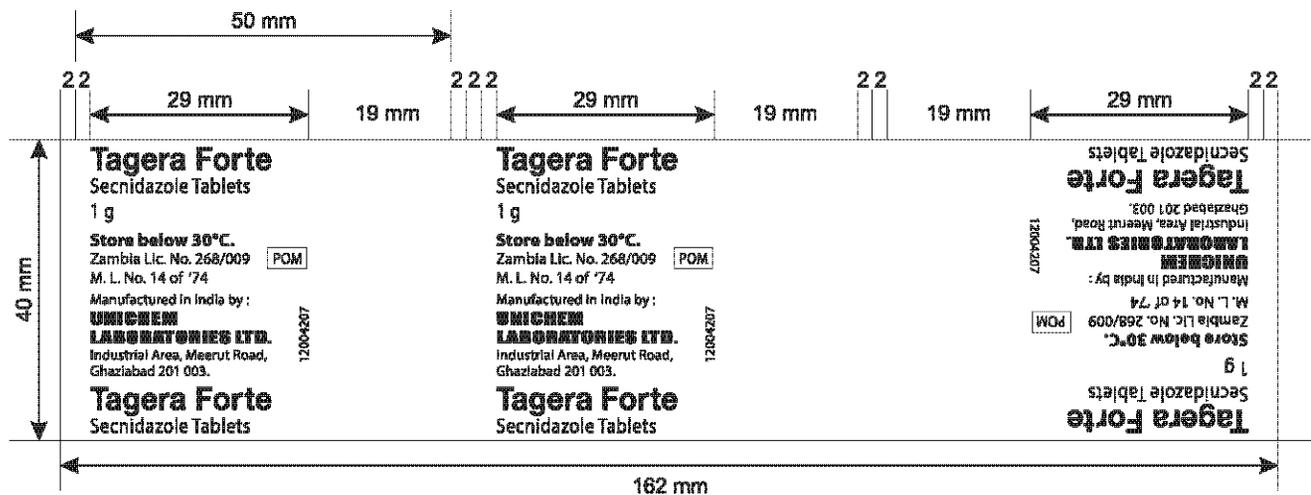
TAGERA FORTE
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1.3 Product Information

1.3.2 Labelling (primary and secondary packaging)

Enclosed overleaf Printed Foil and Carton for TAGERA FORTE (Secnidazole Tablets 1 g).



Company Name : UNICHEM LABORATORIES LTD.		Date: 04-09-2015
Agency Name: Unicorn Creation		Foil Width: 162 mm
Product: Tagera Forte Foil	Packing: 2 Tablets	Blister Size: 50 x 52 mm
Item Code: 12004207	Location: Ghaziabad	Colour Codes: Single colour Black (K 100)
Specification: 0.025 mm blister aluminium foil with VMCH coating. Printing with DSO		Text: Common Export text with 30°C.
Layout No.: Blister Pack Layout No. 10 21 08 300 dated 19-03-1996 of M/s. Precision Gears Pvt. Ltd.		
Reason: The brand name font & the rest text font has been synchronized with the approved fonts on cartons. The text of the artwork has been streamlined with the concurrence of IBD & RA.		

IMPORTANT NOTE : THE PRINTER CAN ASK FOR PRINTED SAMPLE AS COLOUR REFERENCE FOR BETTER REPRODUCTION OF COLOUR SCHEME. DOUBTS REGARDING FONTS/DESIGN/COLOUR SCHEME OR ANY OTHER DISCREPANCY REGARDING THE ARTWORK FILE, DO CONTACT THE PACKAGING DEVELOPMENT DEPARTMENT.



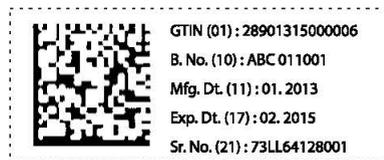
Company Name : UNICHEM LABORATORIES LTD.		Date: 24-7-2017, 12-6-18
Agency Name: UNICHEM ARTLAB		Size: 70 x 70 mm
Product: Tagera Forte - Label	Packing: 10 x 2 Tablets	Barcode: 8901315201927
Item Code: 13009272	Location: Ghaziabad	
Specification: 75 gsm Chromo Paper		Country specific text with 30°C.
Market: Nigeria		
Reason: New artwork specific to Nigeria developed with deletion of design element as per required by NAFDAC authority. 12-6-18: 1g added in generic name.		

Guidelines to printer for processing & printing :

- 5 colour printing job with PANTONE scheme.
- 5 PANTONE colours : Pantone 376 C ■ Pantone 3945 C ■ Pantone Orange 021 C ■ Pantone Process Black C ■ PANTONE 877 C SILVER ■
- Shade that need to appear from the 5 colours to be used for printing : 80% Process Black C
- The printer can ask for printed sample as a colour reference for better reproduction of colour scheme. For doubts, regarding fonts/design/colour scheme or any other discrepancy observed regarding the artwork file, do contact Packaging Development Department.
- Pantone Orange 021 C should appear as it is on the shade card with varnish. i.e. the light, standard and dark shades of orange should be perceptible as Pantone Orange 021 C to human eye



Representation.



GTIN (01) : 28901315000006
 B. No. (10) : ABC 011001
 Mfg. Dt. (11) : 01.2013
 Exp. Dt. (17) : 02.2015
 Sr. No. (21) : 73LL64128001

**Unvarnished Area (60 x 25 mm)
 for overprinting -GS1 2D matrix
 GTIN, Sr.no. along with the Batch no., Mfg. dt.,
 Exp. Dt. & the relevant registration details.**

Company Name : UNICHEM LABORATORIES LTD.		Date: 27-6-2017, 12-6-18
Agency Name: UNICHEM ARTLAB		Size: 54 x 14 x 60 mm
Product: Tagera Forte	Packing: 1 x 2 Tablets	Barcode: 8901315201927
Item Code: 13009271	Location: Ghaziabad	Pharmacode: 3932
Specification: 300 gsm Folding Box Board (CFB)-ITC Cyber XL, with aqua varnish.		Country specific text with 30°C.
Market: Nigeria		
Reason: New artwork specific to Nigeria developed with deletion of design element as per required by NAFDAC authority. 12-6-18: 1g added in generic name.		

Guidelines to printer for processing & printing :

- 5 colour printing job with PANTONE scheme.
- 5 PANTONE colours : **Pantone 376 C** ■ **Pantone 3945 C** ■ **Pantone Orange 021 C** ■ **Pantone Process Black C** ■ **PANTONE 877 C SILVER** ■
- Shade that need to appear from the 5 colours to be used for printing : 80% Process Black C
- The printer can ask for printed sample as a colour reference for better reproduction of colour scheme. For doubts, regarding fonts/design/colour scheme or any other discrepancy observed regarding the artwork file, do contact Packaging Development Department.
- Pantone Orange 021 C should appear as it is on the shade card with varnish. i.e. the light, standard and dark shades of orange should be perceptible as Pantone Orange 021 C to human eye

TAGERA FORTE
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1.3 Product Information

1.3.3 Package insert and patient information leaflet

Enclosed overleaf Package Insert for TAGERA FORTE (Secnidazole Tablets 1g).

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

Tagera Forte

Secnidazole Tablets

COMPOSITION:

Each film coated tablet contains:

Secnidazole..... 1 g

Excipients: Microcrystalline Cellulose, Maize Starch, Gelatin, Sodium Starch Glycolate, Colloidal Anhydrous Silica, Magnesium Stearate, Hypromellose 5 cps, Polyethylene Glycol 6000, Titanium Dioxide, Industrial Methylated Spirit & Dichloromethane.

DOSAGE FORM: Tablets.

CATEGORY OF DISTRIBUTION: Prescription Preparation.

THERAPEUTIC CLASS: Antiprotozoal.

DESCRIPTION OF PRODUCTS: White colored, capsule shaped, film coated tablet with score mark on one side and plain on other side.

DESCRIPTION:

Secnidazole is an orally active 5 - Nitroimidazole with long half-life.

PHARMACOKINETICS:

Secnidazole is rapidly and completely absorbed after oral administration. Following oral administration of secnidazole, the maximum serum level is obtained after 3 hours. Plasma drug concentration are linear over the therapeutic dose range of 0.5 to 2 grams. The plasma elimination half life time is about 20 - 25 hours.

Secnidazole crosses the placental barrier and can be found in maternal milk. Most of the absorbed drug is excreted via urine.

INDICATIONS AND USES:

Secnidazole is indicated for the treatment of intestinal and extra intestinal amoebiasis, trichomoniasis, giardiasis and bacterial vaginosis.

CONTRAINDICATIONS AND PRECAUTIONS:

As in the case of all imidazole derivatives, secnidazole should not be administered during the first trimester of pregnancy or during lactation or in individuals having hypersensitivity to imidazole derivatives. Avoid alcohol and disulfiram during treatment. Avoid use in patients with past history of blood disorders.

ADVERSE EFFECTS:

Secnidazole is well tolerated. Majority of side effects are of mild and transient nature. They include nausea, vomiting, gastralgia, metallic taste, glossitis, stomatitis and urticaria. Vertigo, dizziness, headache and neurological disturbances occur very rarely.

DRUG INTERACTIONS:

Secnidazole may potentiate the anticoagulant effect of warfarin thereby increasing the risk of haemorrhage. Alcoholic beverages should be avoided during the secnidazole therapy and at least one day afterwards because antabuse effect may occur. Similarly consumption of secnidazole with disulfiram should not be allowed in order to avoid occurrence of delirious bouts and confusion.

DOSAGE AND ADMINISTRATION:

Adult:

Intestinal amoebiasis - 2 g single dose
Amoebic liver abscess - 1.5 g per day for 5 days
Trichomoniasis and
Bacterial vaginosis for
patient and partner - 2 g single dose
Giardiasis - 2 g single dose

Children:

Intestinal amoebiasis - 30 mg / kg body weight as single or and giardiasis divided doses.

OVERDOSAGE AND TREATMENT:

To the best of our knowledge, no instances of deliberate or accidental overdose with Secnidazole have been reported so far. In the event of overdosage, supportive and symptomatic therapy is indicated.

STORAGE:

Store below 30°C.

Protect from light & moisture.

Keep all medicines out of reach of children.

NATURE & CONTENT OF CONTAINER (PRESENTATION):

A transparent blister of PVC with a printed aluminum foil as lidding is the container.

2 Tablets are packed in this blister. Blisters & Leaflet in turn are packed in a carton/s.

SHELF LIFE: 24/36 Months. (Please refer on the pack).

Tanzania Registration No. TAN 00,906 P01A UNI

Zambia Lic. No. 268/009

POM

Manufactured in India by :



UNICHEM
LABORATORIES LTD.

Industrial Area, Meerut Road, Ghaziabad 201 003.

13007945

Date of Publication: September, 2015

145 mm

145 mm