

PRODUCT NAME-UNISTEN COMBIPACK PATIENT INFORMATION LEAFLET

UNISTEN COMBIPACK

Unisten Combipack is a pack containing 1 vaginal tablet or **Unisten V1 Vaginal Tablets**, 1 tube of **Unisten Cream** and 1 plastic applicator.

Composition

Unisten V1 Vaginal Tablets

Each tablet contains:
Clotrimazole USP 500mg.

Unisten Cream

Clotrimazole USP 1%
in a water miscible base q.s.

Pharmacological Action

Clotrimazole is an imidazole antifungal with antimicrobial activity which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi. It is reported to be fungistatic at concentrations achieved clinically.

Pharmacokinetics

When applied topically, Clotrimazole penetrates the epidermis but there is little if any systemic absorption. Absorption of 3% to 10% of a dose has been reported following vaginal administration. Clotrimazole is metabolized in the liver to inactive compounds and excreted in the faeces and urine.

Indications

Clotrimazole is a broad spectrum antifungal. It also exhibits activity against *Trichomonas*, *Streptococci*, *Staphylococci* and *Bacteroides*. It is used in cases of *Candidal Vaginitis* and mixed vaginal infections where *Trichomonas* is present or suspected. The cream can also be used for associated vulvitis and to treat the sexual partner to prevent re-infection.

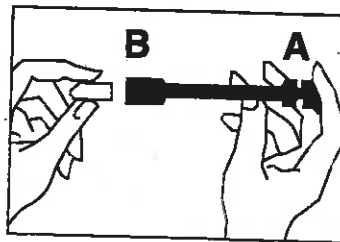
Dosage and Administration

The single Unisten V1 vaginal tablet should be inserted as deeply and comfortably as possible, preferably at night for one night.

The cream should be applied night and morning to the vulva and surrounding area and / or to the partner's penis to prevent re-infection.

Special instructions for Unisten V1 tablet

1. Remove the applicator from the packaging. Pull out plunger A until it stops. Remove the vaginal tablet from the blister pack and place the vaginal tablet firmly into the applicator B.



2. Carefully put the applicator as deeply as is comfortable into the vagina, this is best achieved when lying on the back with legs pulled in a little towards the body.

