

№ UA/16135/01/01
від 04.07.2017

ИМЕЧАТКА: Svizzera Europe BV
 Antennestraat 84, 1322 AS Almere
 P.O.Box 60300, 1320 AJ Almere
Идепнамд
 Тел.: +31 (0) 36 539 73 40
 Факс: +31 (0) 36 539 73 49
www.svizzera-europe.org

Інформація про застосування лікарського засобу, затверджена згідно з нормативними вимогами ВООЗ

До реєстраційного посвідчення

№ UA/16135/01/01

Від 04.07.2018

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

RIFAMPICIN 150mg / ISONIAZID 75 mg TABLETS

Composition

Each film coated tablet contains :

Rifampicin BP 150 mg

Isoniazid BP 75 mg

Pharmacology

Rifampicin: In tuberculosis, rifampicin is bactericidal for both intracellular and extracellular micro-organisms. Microbial resistance to rifampicin can develop, although certain rifampicin - resistant bacteria have decreased virulence. It is unusual to encounter initial resistance. Rifampicin has been shown to inhibit certain DNA viruses such as herpes, adenovirus and pox virus, but at concentrations 500 - 1000 times higher than those required to inhibit the growth of bacteria.

Isoniazid (INH): INH is bactericidal in vitro and in vivo against actively dividing tubercle bacilli; it is less active against non-dividing tubercle bacilli. Its primary action is to inhibit the synthesis of long chain mycolic acids which are unique constituents of mycobacterial cell walls. Isoniazid in low concentrations may prevent elongation of the very long chain fatty acid precursor of the mycolic acids. Since mycolic acids are unique to mycobacteria this explains the high degree of selectivity of Isoniazid for these bacteria. Isoniazid may also have effects of nucleic acid biosynthesis and glycolysis.

INH concentrations of 600 mg/l or greater are required to inhibit Gram-positive and Gram-negative bacteria, but the minimum inhibitory concentration for *M. tuberculosis* is 0.05 - 0.025 mg/l

Actions

It is known that *Mycobacterium tuberculosis* exists as different sub-populations with different growth characteristics and these can be present at the same time in any patient. This makes multidose therapy essential.

Isoniazid is particularly effective against strains of tubercle bacilli which grow rapidly in the oxygen-rich and neutral pH environment of the cavity walls. Rifampicin is most effective against the subpopulation present mainly in the caseous material where the pH is neutral and oxygenation poor. These strains are capable of sudden spurts of active growth and bactericidal action of rifampicin comes into full play against them.

Indications

The combination is indicated in chemotherapy of tuberculosis, short course chemotherapy of pulmonary tuberculosis, intermittent chemotherapy of pulmonary tuberculosis and in treatment of other forms of tuberculosis.



Dosage

As directed by the Physician.

Contraindications

1. Hypersensitivity to any component
2. Impaired liver function
3. Caution in pregnancy.

Side effects

Rifampicin : Gastrointestinal disturbances such as heartburn, epigastric distress, anorexia, vomiting, gas, cramps and diarrhoea have been noted in some patients. Headache, drowsiness, fatigue, ataxia, dizziness, inability to concentrate, mental confusion, visual disturbances, muscular weakness, fever, pains in the extremities, pruritus, urticaria, skin rashes and eosinophilia, sore mouth and sore tongue have occasionally been encountered. Hepatotoxicity has been reported in man usually beginning with two weeks of the start of treatment. There are several reports of hepatotoxicity from rifampicin with isoniazid.

Isoniazid : The common side effects associated with INH are nausea, vomiting, diarrhoea and skin rashes. Severe reactions are almost certainly associated with the presence of an incompletely acetylated hydrazide group. The metabolites acetylisoniazid, isonicotinic acid, isonicotinyl glycine and diacetylhydrazine are much less toxic in animals than are INH and the metabolite monoacetylhydrazine. INH induced peripheral neuropathy may occur in patients on INH and may be more pronounced in malnourished patients. It is attributed to vitamin B₆ deficiency resulting from loss of pyridoxal hydrazone of INH and can be prevented by daily administration of supplementary vitamin B₆.

Incompatibility

Rifampicin : Isoniazid, acetaminophen, alcohol used concurrently with rifampicin may increase hepatotoxic potential of one another. Steroids, anticoagulants, antidiabetic agents, dapsone, digitalis glycosides and quinidine may be required in increased amounts as rifampicin tends to increase their metabolism.

Isoniazid : Isoniazid is an inhibitor of hepatic drug metabolism and may therefore enhance the effects of some drugs taken concomitantly. Inhibition of metabolism may be sufficient with some drugs to produce toxic concentrations and adverse reactions have occurred when isoniazid has been given with anti-epileptics such as phenytoin, primidone, carbamazepine and with benzodiazepines such as diazepam. Theophylline plasma concentrations have increased following several weeks of isoniazid administration.

Special cautions in the use

Urine, faeces, saliva, sputum, sweat, tears may be coloured orange-red by rifampicin and patients should be made aware of this. Caution should be observed in patients with impaired renal function or a history of gout.

Toxic list

None

Presentation

Blister pack of 28 tablets
Blister pack of 10 tablets
Bulk pack of 1000 tablets

Storage and conservation

Store in a cool, dry place below 25°C,
protected from light.

Manufactured by :

Svizera Labs.
Mumbai, India.

Distributed by:

Svizera Europe B.V.
Almere, The Netherlands

1026-1C

