Swidon®

5 mg Tablets

swipha

Composition

Each tablet contains 5 mg Nitrazepam.

Description
Round, white, one-sided scored tablets with **Swidon**® 5 inscribed on one side and SWIPHA on the other side.

Clinical Pharmacology

Pharmacodynamic properties
Pharmacotherapeutic group: Hypnotic and sedatives, Benzodiazepine derivatives. **Swidon**® is a benzodiazepine compound with sedative properties. It acts in 30 to 60 minutes to produce sleep lasting 6 to 8 hours.

Pharmacokinetic

Absorption
The drug is well absorbed form the GI tract with peak blood levels being achieved within 2 hours of administration. Two hours after administration, the concentration of nitrazepam in the cerebrospinal fluid is about 8% and after 36 hours approximately 16% of the concentration in the plasma. The cerebrospinal fluid concentration thus corresponds to the non-protein-bound fraction of active ingredient in the plasma. Steady-state levels are achieved within 5 days.

Half-Life
The half-life is on average 24 hours.

Distribution
In younger persons the volume of distribution is 2L/kg, in elderly patients the volume of distribution is greater, and the mean elimination half-life rises to 40 hours.

Biotransformation
Nitrazepam undergoes biotransformation to a number of metabolites, none of which possess significant clinical activity

Elimination
About 5% of the metabolites are excreted unchanged in the urine together with less than 10% each of the 7-amino- and 7-acetylamino-metabolites in the first 48 hours. In elderly patients with greater volume of distribution, the mean elimination half-life rises to 40 hours.

Indications
Sleep disturbances due to irritability, over-work, conflicts, anxiety, worry, tension and stress; organic sleep disturbances in conjunction with specific therapy.

Dosage and Administration
Adult: 1 tablet (5mg) before retiring to bed.

This average dosage may, if necessary, be increased up to 10mg for outpatients and up to 20mg for inpatients.

Elderly or debilitated patients: Elderly or debilitated patients: the elderly or patients with impaired renal and/or hepatic function will be particularly susceptible to the adverse effects of **Swidon**®. Doses should not exceed half of the dose normally recommended. If organic brain changes are present, the dosage of **Swidon**®should not exceed 1 tablet (5mg) in these patients.

Interactions
Enhancement of the central depressive effect may occur if benzodiazepines are combined with centrally-acting drugs such as neuroleptics, tranquillisers, antidepressants, hypnotics, analgesics and anaesthetics, anti-epileptics and sedative antihistamines. In the case of narcotic analgesics, enhancement of the euphoria may also occur, leading to an increase in psychological dependence. The elderly require special supervision.

The concomitant use of sedative medicines such as benzodiazepines or related drugs such as **Swidon**® with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited.

When **Swidon**® is used in conjunction with anti-epileptic drugs, side-effects and toxicity may be more evident, particularly with hydantoins or barbiturates or combinations including them. This requires extra care in adjusting dosage in the initial stages of treatment.

Known inhibitors of hepatic enzymes, particularly cythochrome P450 have been shown to reduce the clearance of benzodiazepines and may potentiate their action and known inducers of hepatic enzymes, e.g. rifampicin, may increase the clearance of benzodiazepines.

Concomitant intake with alcohol should be avoided. The sedative effect may be enhanced when the product is used in combination with alcohol. This adversely affects the ability to drive or use machines.

Contraindications
Patients with hypersensitivity to benzodiazepines, nitrazepam.

Hypersensitivity reactions with the benzodiazepines including rash, angioedema and hypertension have been reported on rare occasions in susceptible patients.

Use of this drug is also contraindicated in patients with acute pulmonary insufficiency; respiratory depression; phobic or obsessional states; chronic psychosis; myasthenia gravis; sleep apnoea syndrome.

Warnings/Precautions
In patients with chronic pulmonary insufficiency, and in patients with chronic renal or hepatic disease, dosage may need to be reduced.

In elderly, bed-ridden patients, bronchial hypersecretion and excessive salivation leading to aspiration/ pneumonia may occur on rare occasions.

With **Swidon**® as with other hypnotics, patients should avoid taking alcohol while under the influence of the treatment, since the individual response cannot be foreseen. Like all medicaments of the type, **Swidon**® may modify the patient's reactions (driving ability, behaviour in traffic, etc) to a varying extent depending on dosage, administration and individual susceptibility. Since elderly patients are often particularly sensitive to drugs, the dosage should be adapted accordingly. If **Swidon**® is combined with centrally acting drugs such as neuroleptics, tranquilizers, antidepressants, hypnotics, analgesics and anesthetics, it should be borne in mind that their sedative effect may be intensified. This reinforcement can sometimes be made use of therapeutically.

Pregnancy and Lactation

Pregnancy:
There is no evidence as to drug safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. Do not use during pregnancy, especially during the first and last trimesters, unless there are compelling reasons.

If the product is prescribed to a woman of childbearing potential, she should be warned to contact her physician regarding discontinuance of the product if she intends to become or suspects that she is pregnant.

Administration of benzodiazepines in the last trimester of pregnancy or during labour has been reported to produce irregularities in the foetal heart rate, and hypotonia, poor sucking, hypothermia and moderate respiratory depression in the neonate.

Infants born to mothers who took benzodiazepines chronically in the latter stages of pregnancy may have developed physical dependence and may be at some risk of developing withdrawal symptoms in the postnatal period.

Breast-feeding:
Since benzodiazepines are found in the breast milk, the use of **Swidon**® in mothers who are breast-feeding should be avoided.

Adverse Reactions
Common adverse effects include drowsiness during the day, numbed emotions, reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, ataxia and double vision. These phenomena are dose related and occur predominantly at the start of therapy, they usually disappear with repeated administration. The elderly are particularly sensitive to the effects of centrally-depressant drugs.

Anterograde amnesia may occur at therapeutic dosages, the risk increasing at higher dosages. Amnesia may be combined with behavioural problems.

Pre-existing depression may be unmasked during benzodiazepine use.

Other adverse effects are rare and include vertigo, hypotension, gastro-intestinal upsets, skin rashes, visual disturbances, changes in libido, and urinary retention. Isolated cases of blood dyscrasias and jaundice have also been reported.

Use (even at therapeutic doses) may lead to the development of physical and psychological dependence: discontinuation of the therapy may result in withdrawal or rebound phenomena, a transient syndrome whereby the symptoms that led to treatment with benzodiazepine or benzodiazepine-like agent recur in an enhanced form. It may be accompanied by other reactions including mood changes, anxiety and restlessness. Since the risk of withdrawal phenomena/rebound phenomena is greater after abrupt discontinuation of treatment, it is recommended that the dosage be decreased gradually.

Abuse of benzodiazepines has been reported.

Symptoms of Overdosage and Antidotes
When taken alone in overdosage **Swidon**® presents few problems in management and should not present a threat to life unless combined with other CNS depressants (including alcohol).

In the management of overdose with any medicinal product, it should be borne in mind that multiple agents may have been taken.

Symptoms:
Overdosage of benzodiazepines is usually manifested by degrees of central nervous system depression ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion, dysarthria and lethargy; in more serious cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression, rarely coma and very rarely death.

Management:
Following overdose with oral benzodiazepines, vomiting should be induced (within one hour) if the patient is conscious, or gastric lavage undertaken with the airway protected if the patient is unconscious. If there is no advantage in emptying the stomach, activated charcoal should be given to reduce absorption.

Special attention should be paid to respiratory and cardiovascular functions in intensive care. The value of dialysis has not been determined. Flumazenil is a specific IV antidote for use in emergency situations. Patients requiring such intervention should be monitored closely in hospital.

The benzodiazepine antagonist flumazenil is not indicated in patients with epilepsy who have been treated with benzodiazepines. Antagonism of the benzodiazepine effect in such patients may trigger seizures.

If excitation occurs, barbiturates should not be used.

Storage Condition:
Store below 30°C
Protect from light.

Presentation:
Packs: 1 x 10, 3 x 10, 10 x 10 and 20 x 10

Medicine: Keep out of the reach of children

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Manufactured in Nigeria by
swiss pharma nigeria Ltd.,
5, Dopemu Road, Agege, Lagos.

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