Span®

Drotaverine

Description
Span® is a preparation of Drotaverine which is widely used for the treatment of smooth muscle spasm and other allied clinical conditions.

Mode of action
Drotaverine (**Span®**) is a spasmolytic agent which acts directly on smooth muscle cells by adsorption on the cell surface. **Span®** inhibits the phosphodiesterase enzyme which leads to an increase of the cAMP level producing smooth muscle cell relaxation. It is thought that **Span®** also inhibits the initial calcium uptake of the cell. **Span®** is characterized by a rapid onset of action which is very advantageous in cases of acute painful spastic conditions. Because of its direct action on smooth muscle, **Span®** does not affect the autonomic nervous system. Therefore **Span®** is free of the side effects associated with anticholinergic antispasmodics and can be used in glaucoma and prostatic hypertrophy.

Pharmacokinetics
Drotaverine is rapidly and completely absorbed after oral administration. It binds highly (95–98%) to plasma proteins, especially albumin, gamma and beta globulins. The maximum concentration in the blood after oral administration is reached within 45–60 minutes. 65% of the administrated dose is released into the bloodstream in unchanged form after the primary metabolism. It is metabolized in the liver. The half-life of Drotaverine is 8–10 hours. In 72 hours Drotaverine is almost completely excreted from the body, more than 50% is excreted in the urine and about 30% with the feces. Drotaverine is excreted in the form of metabolites and it is not found unchanged in the urine.

Composition
Span® Tablet: Each tablet contains Drotaverine Hydrochloride INN 40 mg.

Indications
- Spastic conditions of the gastrointestinal tract, irritable bowel syndrome.
- Biliary colics and spastic conditions of the biliary tract: Cholecystolithiasis, cholecystitis, cholangitis.
- Renal colics and spastic conditions of the urogenital tract: Nephrolithiasis, ureterolithiasis, pyelitis, cystitis.
- Spastic conditions of the uterus: Dysmenorrhea, imminent abortion, uterine tetanus.

Dosage & administration
Span® Tablet
Adults: 1 to 2 tablets, 3 times daily.
Children (over 6 years): 1/2 to 1 tablet, 1-2 times daily.
Children (1-6 years): 1/4 to 1/2 tablet, 1-2 times daily.

Contraindications
Hypersensitivity to Drotaverine or to any excipient of the medicinal product. Severe hepatic, renal or heart failure (Low cardiac output syndrome).

Side effects
Gastrointestinal Disorders (Rarely Nausea, Vomiting, Constipation), Nervous System Disorders (Rarely Headache, Dizziness, Insomnia), Cardiac Disorders (Rarely Rapid Heartbeat, Hypotension) and Immune System Disorders (Rarely Allergic Reactions including Angioedema, Urticaria, Skin Rash, Itching, Skin Flushing, Fever, Chills, Weakness etc.).

Use in pregnancy & lactation
There is no known case of teratogenecity in animal studies. However, the use of Drotaverine should be avoided during pregnancy and lactation.

Precautions
Caution should be taken for patients suffering from liver and kidney disease.

Drug Interaction
With the simultaneous use of the drug with levodopa it may decrease antiparkinsonic effect of the latter. This combination should be used with caution since the antiparkinsonian effect of levodopa is reduced and the rigidity and the tremor are intensified.

Over dosage
With a significant overdose of Drotaverine, cardiac rhythm and conduction disorders were observed including a complete blockade of the Gis beam and cardiac arrest which can be lethal. In case of overdose, the patient should be under the close medical supervision and receive symptomatic and supportive treatment including induction of vomiting and/or gastric lavage.

Storage
Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Span® Tablet: Each carton contains 20X5 tablets in blister pack.

Opsonin Pharma
Ideas for healthcare

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Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.