Drotaverine, 40 mg, 80 mg, film-coated tablets

Drotaverine, 40 mg/ml, oral suspension

Key facts about active substance:

- Drotaverine, as a isoquinoline derivative acts spasmolytically on smooth muscle.
- Drotaverine is effective in treating smooth muscle spasms of both nervous and muscular origin. Regardless of the type of autonomic innervation drotavinin acts on smooth muscle found in the gastrointestinal tract, bile ducts, urogenital system and and circulatory system;
- The overall net sale in 2016 for drotaverine containg products of Sanofi equaled EUR 82 million.
- To date there is no drotaverine product on the EU market in a form of suspension for paediatric population.

Therapeutic classification: Alimentary tract and metabolism; drugs for functional gastrointestinal disorder, papaverine and derivatives, drotaverine, ATC A03AD02

Drotaverine indications:

Smooth muscle spasticity associated with biliary diseases: biliary lithiasis, cholecystitis, some follicular inflammation, inflammation of the bile ducts, inflammation of the papilla of Vater

Urinary tract smooth muscle spasticity: nephrolithiasis, urolithiasis ureters, inflammation of the renal pelvis, cystitis, painful urge to urinate

As supportive therapy can be used safely and with the desired effect:

- in spastic conditions of gastrointestinal smooth muscle: gastric ulcers and duodenal ulcers, gastritis, enteritis, colitis, spastic of cardia and pylorus of the stomach, irritable bowel syndrome, constipation against the spastic bowel and flatulence, pancreatitis;
- in gynecological diseases: dysmenorrhea;
- tension headaches.

Project status: **Completed stages (IP rights and know-how for the documentation):**

- Pharmacokinetic study to investigate the linearity in PK of drotaverine has been conducted with the reference products.
- Analytical methods for characterization of API and drug products have been validated.
- The solid product formulations (40 mg and 80 mg film-coated tablets) with a similar dissolution profile to the reference product have been developed.
- The composition of the oral suspension (40 mg/5ml) which masking the extremely bitter taste of drotaverine has been preliminary developed.

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Manufacturer GMP approvals: EU GMP