Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Dekolik Syrup

2. Qualitative and quantitative composition

Each 5ml Syrup contains 7.5mg of Prifin Bromide.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Syrup.

A deep – orange syrupy liquid with a characteristic taste.

4. Clinical particulars

4.1 Therapeutic indications

-Pain due to the gastrointestinal spasms and hypermotility: gastritis, gastro-duodenal ulcer, enteritis, colitis, post-gastrectomy syndrome.
-Pain due to the bile duct spasm and dyskinesia: cholecystitis, and cholelithiasis. Pain due to pancreatitis.
-Pain due to urinary tract spasm: lithureteria, vesical tenesmus, cystitis and pyelitis.
-Premedication for gastric endoscopy and gastrointestinal radiography.
-Vomiting.

4.2 Posology and method of administration

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Infants and children:
Under 3 months old – 1 ml every 6-8 hours
3-6 months old – 1-2 ml every 6-8 hours
6-12 months old – 2 ml every 6-8 hours
1-2 years old – 5 ml every 6-8 hours
2-6 years old – 5-10 ml every 6-8 hours
6-12 years old – 10-20 ml every 6-8 hours

Adults and children at the age of 12 years of old and older: 30 - 60 mg (20 - 40 ml) of a syrup 3 times a day.

The treatment duration is 7 - 15 days.

4.3 Contraindications
Hypersensitivity to prifinium bromide and any component of the preparation. Glaucoma, degree III prostatic hypertrophy, acute urinary retention.

4.4 Special warnings and precautions for use
Warnings: A diabetic or Hypertensive patient need to be warned about few drug interactions. A known hypersensitivity patient needs to be careful about the reactions or anaphylactic shock. A pregnant woman or a breastfeeding woman should be warned of certain medications. A Hepatitis [liver disease] patient or a cardiac patient should avoid few drugs.

Precautions :
Certain people who are very sick or very old or who are sensitive show an exacerbation of side effect of the drug which can turn dangerous at times. So, it is very important to remember the precautions while taking the medicine. Pregnancy and Breastfeeding are also special categories wherein extra care or precaution is needed when taking a drug. Few patients may have a hypersensitivity reaction to few medications, and that can be life-threatening rarely. Penicillin hypersensitivity is one example. Diarrhea, rashes are few other symptoms which need a watch. A patient with other co-existing diseases like liver disease, heart disease, kidney disease should take special precautions.

Prostatic hypertrophy, hyperthyroidism, CHF, arrhythmia, ulcerative colitis or those exposed to high environmental temperature. May impair ability to drive or operate machinery. Pregnancy.

4.5 Interaction with other medicinal products and other forms of interaction
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
Action potentiated by tricyclic antidepressants (TCAS), Phenothiazines and MAOs

4.6 Fertility, pregnancy and lactation
No information available

4.7 Effects on ability to drive and use machines
If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using Prifinium Bromide medicine then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively. Pharmacists also advise patients not to drink alcohol with medicines as alcohol intensifies drowsiness side-effects. Please check for these effects on your body when using Prifinium Bromide. Always consult with your doctor for recommendations specific to your body and health conditions.

4.8 Undesirable effects
Such allergic reactions as angioedema, urticaria, hyperemia, itching can develop in patients with hypersensitivity. In rare cases the following reactions are possible: dry mouth, accommodation disorder, constipations, hot flash, tachycardia, hypertension, headache, asthenia, urinary retention, blurred vision, nausea

4.9 Overdose
Symptoms

Management of overdoses

. 🎬 Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Prifinium Bromide, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.
🎬 Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action: Prifinium bromide is a quaternary ammonium antimuscarinic. It inhibits hyperkinesia of the digestive organs and urinary tract, and has a spasmolytic action.

PHARMACODYNAMIC:

5.2 Pharmacokinetic properties
The pharmacokinetics of prifinium bromide, a specific antispasmodic agent, after oral (60 mg) and i.v. (7.5 mg) administration was studied in six healthy male volunteers. After i.v. administration, the drug was rapidly cleared from the serum. Individual serum levels were described by a bi-exponential equation and mean elimination half-life was 2.13 h. The volume of distribution at steady state was about 190% of body weight, and the total serum clearance and renal clearance were 12.5 and 5.80 ml/(min. kg), respectively. The drug reached maximum serum levels (6.76-14.3 ng/ml) within 2-3 h after administration of tablets: the apparent biologic half-life after oral dosing was 2.18 h. The oral bioavailability was low (3.4%), as expected for quaternary ammonium compounds, but the inter-individual variation of bioavailability was small.
5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. Pharmaceutical particulars

6.1 List of excipients
Propylene Glycol

Glycerine
Sodium Benzoate
Sorbitol 70% Solution
Monosodium Citrate Anhydrous
Sucralose
Peach Flavour
FD & C Red # 40Dye

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3years.

6.4 Special precautions for storage
Store below 30 ° C.

6.5 Nature and contents of container
Dekolik Syrup is packaged in Amber Pet plastic bottle
Pack sizes of: 60 ml.

6.6 Special precautions for disposal and other handling
No special requirements for disposal

7. **Applicant /Manufacturer**
Afrab Chem Limited
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