DIPHENOXYLATE

Indications:
Adjunct to rehydration in acute diarrhea, control of faecal consistency after colostomy or ileostomy

Pharmacological Category:
Antidiarrheals

Pregnancy:
Pregnancy category: C
There are no adequate and well-controlled studies in pregnant women. This product should be used during pregnancy only if the anticipated benefit justifies the potential risk to the fetus.

Lactation:
Atropine and, possibly, diphenoxylate metabolite distributed into breast milk; use with caution

Side effects:
Common adverse effects are as follow:
Bloating, constipation, loss of appetite, stomach pain (severe) with nausea and vomiting, blurred vision or changes in near vision, drowsiness, dryness of mouth, nose, and throat, fast heartbeat, shortness of breath or troubled breathing, unusual excitement, nervousness, restlessness, or irritability, unusual warmth, dryness, and flushing of the skin

Contraindications:
 Hypersensitivity to diphenoxylate or atropine
 Obstructive jaundice
 Diarrhea associated with pseudomembranous enterocolitis or infectious enterotoxin-producing bacteria
 blockage of the stomach or bowel, angle-closure glaucoma, myasthenia gravis, urinary blockage, excess acid in the stomach or throat, esophagus problems (eg, difficulty swallowing, inflammation), bowel muscle weakness, or heart problems with severe bleeding

Interactions:
Known drug interactions include barbiturates, tranquilizers, and alcohol. Diphenoxylate hydrochloride and atropine sulfate may interact with MAO inhibitors.
In studies with male rats, diphenoxylate hydrochloride was found to inhibit the hepatic microsomal enzyme system at a dose of 2 mg/kg/day. Therefore, diphenoxylate has the potential to prolong the biological half-lives of drugs for which the rate of elimination is dependent on the microsomal drug metabolizing enzyme system.

Dose:
Adult:
5 mg diphenoxylate/0.05 mg atropine PO q6hr; not to exceed 20 mg diphenoxylate daily
Maintenance: As low as ¼ of initial dosage
Pediatric:
<2 years: Safety and efficacy not established
2-12 years: liquid form is used, diphenoxylate 0.3-0.4 mg/kg/day divided q6hr PO; not to exceed 10 mg/day
>12 years: 5 mg diphenoxylate/0.05 mg atropine PO q6hr; not to exceed 20 mg diphenoxylate daily
Maintenance: As low as ¼ of initial dosage

Administration:
Improvement of symptoms expected within 48 hours; if no improvement within this time, drug is unlikely to be effective.
In doses used for the treatment of diarrhea, whether acute or chronic, diphenoxylate has not produced addiction.

Dosage Form:
Each oral tablet contains 2.5mg diphenoxylate HCl + 25mcg atropine sulfate

References:

1) Lexicomp,s Drug Reference Handbooks, American Pharmacists Association, 20th edition, pages 525-526
2) https://www.drugs.com/pro/diphenoxylate-and-atropine.html
3) British National Formulary 68, September 2014- March 2015, page 59
4) http://reference.medscape.com/drug/lomotil-lonox-diphenoxylate-hcl-atropine-342039
5) https://www.drugs.com/cdi/atropine-diphenoxylate.html
com/drugs/drug-157-levora+015-30+21+oral.aspx?drugid=157&drugname=levora+015-30+21+oral
2) http://reference.medscape.com/drug/mylicon-phazyme-simethicone-342005#0
3) http://www.pdr.net/drug-summary/Gas-X-simethicone-2675