DOCQLACE - docusate sodium syrup
Qualitest Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DocQLace Syrup

Active Ingredient (in each 15 mL (1 tablespoonful)) :Docusate sodium 60 mg

Purpose: Stool Softener

Uses

- for gentle, reliable relief from occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

- laxative products for longer than 1 week unless told to do so by a doctor
- if you are presently taking mineral oil unless told to do so by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last over two weeks

Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take as directed by a doctor
- doses must be given in a 6 to 8 oz glass of milk or fruit juice, to prevent throat irritation
- take only by mouth. Dose may be taken as a single daily dose or in divided doses.
- dosage should be adjusted to individual response

adults and children 12 years of age and older	1 to 6 tablespoonfuls, or as directed by a doctor
children 6 to under 12 years of age	1 to 2 1/2 tablespoonfuls, or as directed by a doctor
children under 6 years	Ask a doctor

Other information

- Store at room temperature 20° -25°C.
- Protect from freezing and excessive heat

You may report serious side effects to:

130 Vintage Drive, Huntsville, AL 35811

Inactive ingredients

alcohol (not more than 1%), citric acid, D&C red no. 33, FD&C red no.40, peppermint flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium benzoate, sodium citrate, sucrose.

Manufactured for:

Qualitest Pharmaceuticals
Huntsville, AL 35811 USA

Drug Facts

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If pregnant or breast feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions ■ take as directed by a doctor ■ doses must be given in a 6 to 8 oz glass of milk or fruit juice, to prevent throat irritation ■ take only by mouth. Dose may be taken as a single daily dose or in divided doses. ■ dosage should be adjusted to individual response

adults and children 12 years of age and older	1 to 6 tablespoonfuls, or as directed by a doctor
children 6 to under 12 years of age	1 to 2 ½ tablespoonfuls, or as directed by a doctor
children under 6 years	ask a doctor

Other information ■ store at room temperature 20°-25°C (68°-77°F) ■ protect from freezing and excessive heat

You may report serious side effects to:
130 Vintage Drive, Huntsville, AL 35811.

Inactive ingredients alcohol not more than 1%, citric acid, D&C red no. 33, FD&C red no. 40, peppermint flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium benzoate, sodium citrate, sucrose

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Manufactured for:
QUALITEST PHARMACEUTICALS
HUNTSVILLE, AL 35811 USA
Rev. 12/10

Control # Exp. Date

NDC 0603-0747-58

DOCQLACE SYRUP

Stool Softener
Stimulant Free

Docusate Sodium 20 mg/5 mL
Contains not more than 1% alcohol

BULK CONTAINER – NOT FOR HOUSEHOLD USE
Pharmacist - Dispense in a tight, light-resistant container with child-resistant closure.

TAMPER EVIDENT: Do not use if tamper-evident safety seal around cap is broken or missing

473 mL (1 Pint)

Qualitest®

DOCQLACE
docusate sodium syrup

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:0603-0747
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Docusate sodium (Docusate)	Docusate sodium	20 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid	
D&C red no. 33	
methylparaben	
propylene glycol	
propylparaben	
sodium citrate	
water	
sodium benzoate	
sucrose	
FD&C red no. 40	
alcohol	
glycerin	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	PEPPERMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-0747-58	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/05/1990	

Labeler - Qualitest Pharmaceuticals (011103059)