PRODUCT SUMMARY

1. Trade name of the medicinal product

NORSK - NO DATA

2. Qualitative and quantitative composition

NORSK - NO DATA

3. Pharmaceutical form

NORSK - NO DATA

4. CLINICAL PARTICULARS

4.1 Therapeutic indicators

FOR THE PREVENTION AND TREATMENT OF CHRONIC CONSTIPATION.
AS AN ADJUNCT IN ABDOMINAL RADIOLOGICAL PROCEDURES.

4.2 Posology and method of administration

ADULTS AND ELDERLY: UP TO 500 MG DAILY IN DIVIDED DOSES TREATMENT SHOULD
BE COMMENCED WITH LARGE DOSES WHICH SHOULD BE DECREASED AS THE CONDITION OF THE PATIENT IMPROVES.
CHILDREN: NOT RECOMMENDED.
(A PAEDIATRIC LIQUID PREPARATION IS AVAILABLE FOR CHILDREN)
FOR USE WITH BARIUM MEALS : 400 MG TAKEN WITH THE MEAL.

4.3/4.9 Clinical particulars section

A) CONTRAINDICATIONS: DOCUSATE SODIUM SHOULD NOT BE ADMINISTERED WHEN ABDOMINAL PAIN, NAUSEA, VOMITING OR INTESTINAL OBSTRUCTION IS PRESENT.
DOCUSATE SODIUM SHOULD NOT BE GIVEN TO INFANTS UNDER SIX MONTHS.
B) INTERACTIONS: CONCURRENT ADMINISTRATION WITH MINERAL OIL IS CONTRAINDICATED.
ANTHRAQUINONE DERIVATIVES SHOULD BE TAKEN IN REDUCED DOSE WHEN ADMINISTERED WITH DOCUSATE SODIUM AS IT INCREASES THEIR ABSORPTION.
C) EFFECTS ON ABILITY TO DRIVE: NONE STATED.
D) OTHER UNDESIRABLE EFFECTS: NONE STATED.
E) PREGNANCY AND LACTATION: THERE IS INADEQUATE EVIDENCE OF SAFETY OF THE DRUG IN HUMAN PREGNANCY, NOR IS THERE EVIDENCE FROM ANIMAL WORK
THAT IT IS FREE FROM HAZARD, BUT IT HAS BEEN IN WIDE USE FOR MANY YEARS WITHOUT APPARENT ILL CONSEQUENCE. USE IN PREGNANCY ONLY IF THE BENEFITS OUTWEIGH THE POTENTIAL RISKS.
DOCUSATE SODIUM IS EXCRETED IN BREAST MILK AND SHOULD THEREFORE BE USED WITH CAUTION IN LACTATING MOTHERS.
F) OTHER SPECIAL WARNINGS AND PRECAUTIONS: NONE STATED.
G) OVERDOSE: IN RARE CASES OF OVERDOSE, EXCESSIVE LOSS OF WATER AND ELECTROLYTES MAY OCCUR. THIS SHOULD BE TREATED BY ENCOURAGING THE PATIENT TO DRINK PLENTY OF FLUID.
H) INCOMPATIBILITIES (MAJOR): MINERAL OILS.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

DOCUSATE SODIUM IS AN ANIONIC WETTING AGENT WHICH ACTS AS A FAECAL SOFTNER BY LOWERING SURFACE TENSION AND ALLOWING PENETRATION OF ACCUMULATED, HARD, DRY FAECES BY WATER AND FATS.

5.2 Pharmacokinetic properties

DOCUSATE SODIUM EXERTS ITS CLINICAL EFFECT IN THE GASTROINTESTINAL TRACT. THERE IS SOME EVIDENCE THAN DOCUSATE SODIUM IS ABSORBED AND IS
CAPABLE OF ENHANCING ABSORPTION OF CERTAIN COMPOUNDS ADMINISTERED CONCOMITANTLY.

PHARMACEUTICAL PROPERTIES

6.1 List of excipients

NORSK - NO DATA

6.2 Incompatibilites

NORSK - NO DATA

6.3 Shelf life

NORSK - NO DATA

6.4 Special precautions for storage

NORSK - NO DATA

6.5 Nature and contents of container

NORSK - NO DATA

6.6 Instructions for use/handling

NORSK - NO DATA

ADMINISTRATION DETAILS

7. Marketing authorization holder

NORSK - NO DATA

8. Marketing Authorization number

NORSK - NO DATA

9. Date of first authorization/renewal of authorization

NORSK - NO DATA

10. Date of (partial) revision of the text

NORSK - NO DATA