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 TREATMENT OF ACUTE GASTRIC AND DUODENAL ULCERS.

4.2 Posology and method of administration

ADULTS
IN MOST PATIENTS GASTROZEPIN SHOULD BE GIVEN IN A DOSAGE OF 100MG DAILY AS ONE TABLET EACH MORNING AND ONE AT NIGHT, ON AN EMPTY STOMACH, APPROXIMATELY HALF AN HOUR BEFORE MEALS. FREEDOM FROM DISCOMFORT IS USUALLY ACHIEVED WITH GASTROZEPINE AFTER A FEW DROPS BUT TREATMENT SHOULD BE CONTINUED FOR A TOTAL OF 4-6 WEEKS TO ALLOW THE CONDITION TO BE COMPLETELY HEALED. IN PATIENTS WITH SEVERE SYMPTOMS, THE TOTAL DAILY DOSAGE MAY BE INCREASED TO 150 MG, ONE TABLET TO BE TAKEN THREE TIMES A DAY. THERAPY MAY BE CONTINUED FOR UP TO THREE MONTHS.
ELDERLY
THERE IS NO EVIDENCE TO SUGGEST THAT THE DOSAGE SHOULD BE REDUCED IN THE ELDERLY, PROVIDED NORMAL RENAL FUNCTION IS MAINTAINED. THE DOSAGE MAY, HOWEVER, NEED TO BE MONITORED IN PATIENTS WITH RENAL IMPAIRMENT, PARTICULARLY THOSE WITH END-STAGE RENAL FAILURE. DOSGE MODIFICATIONS SHOULD TAKE PLACE BY PROLONGATION OF THE DOSAGE INTERVAL.
CHILDREN
NOT RECOMMENDED FOR USE IN CHILDREN UNDER 12 YEARS.

4.3/4.9 Clinical particulars section

A) CONTRAINDICATIONS: THERE ARE NO KNOWN CONTRAINDICATIONS OTHER THAN HYPERSENSITIVITY TO PIRENZEPINE.
B) INTERACTIONS: THERE ARE NO CLINICALLY SIGNIFICANT INTERACTIONS WITH PIRENZEPINE, ALTHOUGH ANTICHOLINERGIC SIDE-EFFECTS MAY BE ENHANCED WHEN GIVEN TOGETHER WITH OTHER DRUGS WITH ANTICHOLINERGIC PROPERTIES, EG. ANTIHISTAMINES, BUTYROPHENONES, PHENOTHIAZINES AND TIRCYCLIC ANTIDEPRESSANTS. THERE IS NO EVIDENCE SO FAR THAT PIRENZEPINE INTERFERES WITH STANDARD LABORATORY TESTS. A PHARMACOLOGICAL INTERACTION BETWEEN SYMPATHOMIMETICS OR MONOAMINE OXIDASE INHIBITORS AND PIRENZEPINE IS A THEORETICAL POSSIBILITY.
C) EFFECTS ON ABILITY TO DRIVE: NOT APPICABLE
D) OTHER UNDESIRABLE EFFECTS: OCCASIONALLY DRY MOUTH AND ACCOMODATION DIFFICULTIES MAY OCCUR, BUT THESE ARE TRANSITORY AND RARELY SUFFICIENTLY SEVERE TO WARRANT DISCONTINUATION OF THERAPY. EXTREMELY RARELY THROMBOCYTOPENIA AND AGRANULOCYTOSIS HAVE BEEN REPORTED.
E) USE IN PREGNANCY AND LACTATION: IN ANIMALS STUDIES PIRENZEPINE HAD NO TERATOGENIC EFFECTS IN THE SPECIES TESTED EVEN AT HIGH DOSES. HOWEVER, THE USE OF THE DRUG IS NOT RECOMMENDED DURING PREGNANCY.

PIRENZEPINE APPEARS IN THE MILK OF LACTATING MOTHERS IN MINIMAL AMOUNTS AFTER THERAPEUTIC DOSES, BUT IT IS NOT LIKELY TO ADVERSELY AFFECT THE INFANT.
F) OTHER SPECIAL WARNINGS AND PRECAUTIONS: PIRENZEPINE SHOULD BE AVOIDED IN PATIENTS WITH PROSTATIC ENLARGEMENT, ORGANIC PYLORIC STENOSIS, PARALYTIC ILEUS, CLOSED ANGLE GLAUCOMA OR THOSE WITH A SHALLOW ANTERIOR CHAMBER.
G) OVERDOSE: SYMPTOMS OF OVERDOSAGE SHOULD WOULD INCLUDE DRYNESS OF THE MOUTH AND VISUAL DISTURBANCE. THERE IS A POSSIBILITY OF DIARRHOEA OR CONSTIPATION, HEADACHE AND MENTAL CONFUSION. THERE IS NO SPECIFIC ANTIDOTE TO PIRENZEPINE. INITIAL TREATMENT OF OVERDOSAGE IS BY EMESIS OR GASTRIC LAVAGE IF APPROPRIATE, OTHERWISE TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.
H) INCOMPATIBILITIES: NOT APPLICABLE

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

PIRENZEPINE IS AN ANTICHOLINERGIC AGENT WITH A SELECTIVE ANTAGONIST ACTION AT MUSCARINIC RECEPTORS (M(1) SUBTYPE).

5.2 Pharmacokinetic properties

ABSORPTION OF PIRENZEPINE AFTER ORAL ADMINISTRATION IS LIMITED AND CONSEQUENTLY BIOAVAILABILITY IS LOW, WITH APPROXIMATELY 26% OF THE DOSE ADMINISTERED REACHING THER PERIPHERAL CIRCULATION. PEAK PLASMA CONCENTRATION AFTER A SINGLE DSOE IS REACHEC WITHIN 2 HOURS OF ADMINISTRATION, WHILST STEADY STATE CONCENTRATIONS ARE REACHED WITHIN 3 DAYS FOLLOWING REPEATED DOSING.
FOLLOWING ABSORPTION, PIRENZEPINE IS DISTRUBUTED WIDELY IN THE BODY AND PROTEIN BINDING IS LOW, OF THE ORDER OF 10%. PIRENZEPINE IS METABOLISED ONLY TO A SLIGHT EXTENT TO DESMETHYLPIRENZEPINE, WITH 80-90% OF THE DRUG BEING EXCRETED UNCHANGED IN THE URINE AND FAECES. THE HALF-LIFE OF PIRENZEPINE IS ON AVERAGE 11-12 HOURS.

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