נובמבר, 2023

TRITACE COMP 2.5mg/12.5mg
TRITACE COMP 5mg/25mg
TABLETS

מרכיבים פעילים:

Ramipril 2.5 mg / Hydrochlorothiazide 12.5 mg
Ramipril 5 mg / Hydrochlorothiazide 25 mg

ההתוויה המאושרת:

Essential hypertension.
Tritace comp is indicated in patients whose blood pressure cannot be adequately lowered with ramipril alone or hydrochlorothiazide alone.

חברת סאנופי מבקשת להודיע על עדכון העלון לרופא.

העדכונים העיקריים הינם:

5.3 Preclinical safety data

Ramipril + Hydrochlorothiazide
In rats and mice the combination of ramipril and hydrochlorothiazide has no acute toxic activity up to 10,000 mg/kg. Repeated doses administration studies performed in rats and monkeys revealed only disturbances in electrolytes balance.
Reproduction studies in rats and rabbits revealed that the combination is somewhat more toxic than either of the single components but none of the studies revealed a teratogenic effect of the combination.
No studies on mutagenicity and carcinogenicity have been performed with the combination ~~as studies with individual components showed no risk~~.
~~Reproduction studies in rats and rabbits revealed that the combination is somewhat more toxic than either of the single components but none of the studies revealed a teratogenic effect of the combination.~~

Ramipril
Extensive mutagenicity testing using several test systems has yielded no indication that ramipril possesses mutagenic or genotoxic properties.
Long-term studies in rat and mouse have yielded no indication of any tumorigenic effect.
Renal tubules with oxyphilic cells and tubules with oxyphilic cellular hyperplasia in rats are regarded as response to functional alterations and morphological changes, and not as a neoplastic or pre-neoplastic response.

Hydrochlorothiazide
Hydrochlorothiazide was not genotoxic in vitro in the Ames mutagenicity assay of Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or in vivo in assays using mouse

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germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the Drosophila sex-linked recessive lethal trait gene. Positive test results were obtained only in the in vitro CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the Aspergillus nidulans non-disjunction assay at an unspecified concentration. Two-year feeding studies in mice and rats conducted under the auspices of the US National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: https://israeldrugs.health.gov.il/#!/byDrug

בברכה,

חברת סאנופי ישראל בע"מ