מרץ 2019

הנדון: רטרוביר קפסולות 250 מ"ג
Retrovir capsules 250 mg

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר **Retrovir capsules 250mg.**
העדכון נוגע לסעיף המינונים. לא מדובר בשינוי במשטר המינון, אלה רק בדגש על שימוש במזרק קטן יותר (שנתות של 0.1 מ"ל) בילודים.
בהודעה זו כלולים השינויים המהותיים בעלון לרופא. בעלון ישנם שינויים נוספים.

מרכיבים פעילים וחוזקם:

Zidovudine – 250mg

התוויה הרשומה לתכשיר בישראל:

Retrovir oral formulations are indicated in anti-retroviral combination therapy for Human Immunodeficiency Virus (HIV) infected adults and children.
Retrovir chemoprophylaxis is indicated for use in HIV-positive pregnant women (over 14 weeks of gestation) for prevention of maternal-foetal HIV transmission and for primary prophylaxis of HIV infection in newborn infants.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא :

4.2 Posology and method of administration

Retrovir should be prescribed by physicians who are experienced in the treatment of HIV infection.

Dosage in adults and adolecents weighing at least 30 kg: The usual recommended dose of Retrovir in combination with other anti-retroviral agents is 250 or 300 mg twice daily.

Dosage in children: Retrovir 100 mg capsules and Retrovir 100 mg/10 ml oral solution are available for use in children.

Weight (kg)	In the morning	In the evening	Daily dose (mg)
8-13	one 100 mg capsule	one 100 mg capsule	200
14-21	one 100 mg capsule	two 100 mg capsules	300
22-30	two 100 mg capsules	two 100 mg capsules	400
Alternatively children weighing at least 28 kg to 30 kg (included) could take:			
28-30	one 250 mg capsule	one 250 mg capsule	500

Oral solution is available for dosing children less than ~~8kg~~8 kg and for those children above ~~8kg~~8 kg unable to swallow capsules (see Oral Solution ~~PI)~~SPC).

Dosage in the prevention of maternal-foetal transmission: Pregnant women (over 14 weeks of gestation) should be given 500 mg/day orally (100 mg five times per day) until the beginning of labour. During labour and delivery Retrovir should be administered intravenously at 2 mg/kg bodyweight given over one hour followed by a continuous intravenous infusion at 1 mg/kg/h until the umbilical cord is clamped.

~~The newborn infants~~Neonates should be given 0.2 mL/kg (2 mg/kg) bodyweight orally every 6 hours starting within 12 hours after birth and continuing until 6 weeks old ~~(e.g. a 3 kg neonate would require a 0.6 ml dose of oral solution every 6 hours).~~ .

Care should be taken when calculating doses for neonates due to the small volumes of oral solution required. To facilitate dosing precision, an appropriately sized syringe with 0.1 mL graduation should be used to ensure accurate oral dosing of neonates (see oral solution SPC).

Infants unable to receive oral dosing should be given Retrovir intravenously at 1.5 mg/kg bodyweight infused over 30 minutes every 6 hours.

In case of planned caesarean, the infusion should be started 4 hours before the operation. In the event of a false labour, the Retrovir infusion should be stopped and oral dosing restarted.

Dosage adjustments in patients with haematological adverse reactions: Substitution of zidovudine should be considered in patients whose haemoglobin level or neutrophil count fall to clinically significant levels. Other potential causes of anaemia or neutropenia should be excluded. Retrovir dose reduction or interruption should be considered in the absence of alternative treatments (see sections 4.3 and 4.4).

Dosage in the elderly: Zidovudine pharmacokinetics have not been studied in patients over 65 years of age and no specific data are available. However, since special care is advised in this age group due to age-associated changes such as the decrease in renal function and alterations in haematological parameters, appropriate monitoring of patients before and during use of Retrovir is advised.

Dosage in renal impairment: The recommended dose for patients with severe renal impairment (creatinine clearance < 10 ml/min) and patients with end-stage renal disease maintained on haemodialysis or peritoneal dialysis is 100 mg every 6 to 8 hrs (300-400 mg daily). Haematological parameters and clinical response may influence the need for subsequent dosage adjustment (see section 5.2).

Dosage in hepatic impairment: Data in patients with cirrhosis suggest that accumulation of zidovudine may occur in patients with hepatic impairment because of decreased glucuronidation. Dosage reductions may be necessary but, due to the large variability in zidovudine exposures in patients with moderate to severe liver disease, precise recommendations cannot be made. If monitoring of plasma zidovudine levels is not feasible, physicians will need to monitor for signs of intolerance, such as the development of haematological adverse reactions (anaemia, leucopenia, neutropenia) and reduce the dose and/or increase the interval between doses as appropriate (see section 4.4).

מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~
תוספת – כתב **כחול**
תוספת החמרה - כתב **כחול** – מסומן בצהוב מרקר

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,
טניה רשקובן
רוקחת ממונה