Sitawok (Sitagliptin) Indication and Usage

Therapeutic Indication of Sitawok (Sitagliptin)

- Sitagliptin is indicated as adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes.

- In combination with Metformin and a PPAR_ agonist, it is indicated as an adjunct to diet & exercise in adult patients with type-2 Diabetes mellitus who are inadequately controlled on combination therapy with Metformin and a PPAR_ agonist.

- It is indicated in combination with insulin, alone or in combination with Metformin.

Limitations of Use

- Sitawok (Sitagliptin) should not to be used in type 1 diabetes.

- Its use has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Sitagliptin.

Posology and method of administration

Recommended Dosing

- The recommended dose of Sitawok (Sitagliptin) is **100 mg once daily**. Sitagliptin can be taken with or without food. It should be swallowed whole. The tablets must not be split, crushed, or chewed before swallowing.

Recommendations for Use in Renal Impairment

- For patients with an estimated glomerular filtration rate [eGFR] greater than or equal to 45 mL/min/1.73 m2 to less than 90 mL/min/1.73 m2, no dosage adjustment for Sitagliptin is required.
- For patients with moderate renal impairment (eGFR greater than or equal to 30 mL/min/1.73 m2 to less than 45 mL/min/1.73 m2), the dose of Sitagliptin is **50 mg once daily.**
- For patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m2) or with end-stage renal disease (ESRD) requiring haemodialysis or peritoneal dialysis, the dose of Sitagliptin is **25 mg once daily.**

- Sitagliptin may be administered without regard to the timing of dialysis.
- Because there is a need for dosage adjustment based upon renal function, assessment of renal function is recommended prior to initiation of Sitagliptin and periodically thereafter.
- There have been postmarketing reports of worsening renal function in patients with renal impairment, some of whom were prescribed inappropriate doses of Sitagliptin.

Use in special populations

Pregnancy

Pregnancy Category B:

- Reproduction studies have been performed in rats and rabbits. Doses of Sitagliptin up to 125 mg/kg (approximately 12 times the human exposure at the maximum recommended human dose) did not impair fertility or harm the fetus. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

- Sitagliptin administered to pregnant female rats and rabbits from gestation day 6 to 20 (organogenesis) was not teratogenic at oral doses up to 250 mg/kg (rats) and 125 mg/kg (rabbits), or approximately 30- and 20-times human exposure at the maximum recommended human dose (MRHD) of 100 mg/day based on AUC comparisons. Higher doses increased the incidence of rib malformations in offspring at 1000 mg/kg, or approximately 100 times human exposure at the MRHD.

- Sitagliptin administered to female rats from gestation day 6 to lactation day 21 decreased body weight in male and female offspring at 1000 mg/kg. No functional or behavioural toxicity was observed in offspring of rats.

- Placental transfer of Sitagliptin administered to pregnant rats was approximately 45% at 2 hours and 80% at 24 hours post dose. Placental transfer of Sitagliptin administered to pregnant rabbits was approximately 66% at 2 hours and 30% at 24 hours.

Nursing Mothers

- Sitagliptin is secreted in the milk of lactating rats at a milk to plasma ratio of 4:1. It is not known whether Sitagliptin is excreted in human milk.

Because many drugs are excreted in human milk, caution should be exercised when Sitagliptin is administered to a nursing woman.

Lactation

- There is no information regarding the presence of Sitagliptin in human milk, the effects on the breastfed infant, or the effects on milk production. Sitagliptin is present in rat milk and therefore possibly present in human milk.
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Sitagliptin and any potential adverse effects on the breastfed infant from Sitagliptin or from the underlying maternal condition.

Paediatric Use

- Safety and effectiveness of Sitagliptin in paediatric patients under 18 years of age have not been established.

Geriatric Use

- Of the total number of subjects (N=3884) in pre-approval clinical safety and efficacy studies of Sitagliptin, 725 patients were 65 years and over, while 61 patients were 75 years and over. No overall differences in safety or effectiveness were observed between subjects 65 years and over and younger subjects. While this and other reported clinical experience have not identified differences in responses between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.
- This drug is known to be substantially excreted by the kidney. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in the elderly, and it may be useful to assess renal function in these patients prior to initiating dosing and periodically thereafter.

Reference:

- Prescribing information of Product