Physician's Guide: Starting Trobalt: Points to discuss with patients

This guide is not a substitute for Trobalt (retigabine) Summary of Product Characteristics (SPC). Please consult the SPC for full prescribing information.

Dosing

Trobalt must be taken orally in three divided daily doses

- With or without food.
- Tablets should be swallowed whole, and not chewed, crushed or divided.

Trobalt must be titrated to reach an effective dose

- The total starting dose is up to a maximum of 300 mg/day.
- The total daily dose is increased by a maximum of 150 mg/day every week, according to the individual patient response and tolerability.
- The maximum total maintenance dose is 1200 mg/day.

Titrating the dose of retigabine more rapidly than recommended may increase the risk of central nervous system related adverse events, including confusional state, hallucination and psychotic disorders.

Points to discuss with your patients

1. Eye and skin, lip or nail pigment changes (discolourations)

Pigment changes (discolouration) of ocular tissues, including the retina have been reported in long-term clinical studies with Trobalt, sometimes but not always in conjunction with pigment changes of the skin, lips or nails. Reversibility of retinal pigmentation after retigabine discontinuation has been reported in some subjects the long-term prognosis of these findings is currently unknown, but some of the reports have been associated with visual impairment.

Pigment changes (blue gray discolouration) of the skin, lips or nails have been observed, generally at higher doses and after several years of treatment.

In addition a distinct form of macular abnormality with features of vitelliform maculopathy has also been identified, in most cases diagnosed with optical coherence tomography (OCT) imaging. The rate of progression of vitelliform maculopathy and its impact on retinal and macular function and vision is unclear. Vision abnormalities (field constriction, loss of central sensitivity, and reduced visual acuity) have been reported.

- It is recommended that a comprehensive ophthalmological examination (including visual acuity, slit-lamp examination, dilated fundus photography and macular OCT imaging) is performed in all patients at baseline and at least every 6 months.
- If retinal pigment changes, vitelliform maculopathy or vision changes are detected, treatment with Trobalt should only be continued after a careful re-assessment of the balance of benefits and risks. If continued, the patient should be monitored more closely.

Does your patient experience vision changes or skin, lip or nail discolouration?

Has your patient had an ophthalmological examination, as described above?

Does your patient have any feature of acquired vitelliform maculopathy identified during ophthalmological examination?

Trobalt™
retigabine tablets

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.*

Healthcare professionals are asked to report any suspected adverse reactions.

2. Urinary retention

Urinary retention, dysuria and urinary hesitation were reported in controlled clinical studies with Trobalt, generally within the first 8 weeks of treatment.

- Trobalt must be used with caution in patients at risk of urinary retention, and it is recommended that patients are advised about the risk of these possible effects

Does your patient have symptoms of urinary retention, e.g. hesitancy, poor stream?
Does your patient take drugs that can cause urinary retention e.g. anticholinergics?
Is your patient able to communicate new symptoms of urinary retention?

3. QT Interval

A study of cardiac conduction in healthy subjects has demonstrated that Trobalt titrated to 1200 mg/day produced a QT prolonging effect. A mean increase in Individual Corrected QT Interval (QTcI) of up to 6.7 ms (upper bound of 95% one-sided CI 12.6 ms) was observed within 3 hours of dosing.

- Caution should be taken when Trobalt is prescribed with medicinal products known to increase QT interval and in patients with known prolonged QT interval, congestive cardiac failure, ventricular hypertrophy, hypokalaemia or hypomagnesaemia and in patients initiating treatment who are 65 years of age and above
- In these patients it is recommended that an electrocardiogram (ECG) is recorded before initiation of treatment with Trobalt and in those with a corrected QT interval >440 ms at baseline, an ECG should be recorded on reaching the maintenance dose

Does your patient have a history of cardiac disease?
Does your patient take drugs that are known to cause QT prolongation?

Retigabine has not been shown to cause cardiac arrhythmias in the randomised clinical trials, however patients should be advised to report any new symptoms that might indicte a prolonged QT interval, for example palpitations, syncope.

4. Psychiatric effects

During controlled clinical studies, confusional state, psychotic disorders and hallucinations were reported, generally within the first 8 weeks of treatment.

It is recommended that patients are advised about the risk of these possible effects and to not exceed the recommended titration schedule.

Adverse events should be reported to the **Health Products Regulatory Authority (HPRA) using Adverse Reaction Report Form obtained either from the HPRA or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 6764971,** Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

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