Physician Guide:

Starting Trobalt:
Points to discuss with patients

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.

Treatment initiation packs are available for patients using the standard dose titration regimen to facilitate the first 2 weeks of therapy, and reach a potentially therapeutic dose of 600 mg/day by the third week of therapy.

Points to discuss with your patients

Eye and skin, lip or nail pigment changes (discolorations)

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. 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.

- It is recommended that a comprehensive ophthalmological examination (including visual acuity, slit-lamp examination, and dilated fundoscopy) is performed in all patients at baseline and at least every 6 months thereafter while treatment is ongoing.
- If retinal pigment or vision changes are detected, Trobalt should be discontinued unless no other suitable treatment options are available. If continued, the patient should be monitored more closely and the prescriber and the patient should discuss the potential risks assessed against the benefits of maintained treatment with Trobalt.

Does your patient experience vision changes or skin, lip or nail discoloration?
Has your patient had an ophthalmological examination, as described above?

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Trobalt®
retigabine tablets

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?

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 new symptoms that might indicate a prolonged QT interval, for example palpitations, syncope.

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.

THE LATEST, FULL PRESCRIBING INFORMATION FOR THIS PRODUCT IS IN ATTACHMENT.
In order to ensure that this product information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest Prescribing Information which is available from GlaxoSmithKline (Malta) Ltd (Tel: +356 21238131) or alternatively, on the website of the European Medicines Agency http://www.ema.europa.eu.

REPORTING ADVERSE EVENTS (AEs):
Malta & Gibraltar: **If you become aware of any AEs, medication errors and/or use during pregnancy in association with GSK products, please report the event promptly to:** GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta (Tel: +356 21238131)

Malta: alternatively, any suspected AEs and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system:
Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Gibraltar: **alternatively, any suspected AEs and medication errors can also be reported via the UK regulatory authority (MHRA):** https://yellowcard.mhra.gov.uk/

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