

Tayside D&TC Supplement No. 27

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Produced by Tayside New Medicines Implementation Panel (NMIP)

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Scottish Medicines Consortium (SMC) Advice Issued in June 2003

Olanzapine (Zyprexa®) – acute mania

➤ Restricted use

- Olanzapine is the first atypical antipsychotic to be licensed for the treatment of moderate to severe manic episode. It can be used as monotherapy or in combination with lithium or valproate semisodium.

Points for local consideration:

- Olanzapine is at least as effective as comparator treatments (haloperidol, lithium, valproate semisodium) in the treatment of acute mania.
- Olanzapine is associated with fewer extrapyramidal side-effects versus haloperidol.
- The management of mania is complex due to the variable presentation of the condition, the wide range of treatment options and a lack of clear guidance on their optimum use.
- Olanzapine has not been demonstrated to prevent recurrence of manic or depressive episodes. The majority of prescribing is anticipated to take place in secondary care for treatment of the acute phase.
- The use of olanzapine in acute mania is restricted to patients under the overall supervision of clinicians experienced in managing this complex disorder.

Vardenafil (Levitra®) – erectile dysfunction (ED)

➤ Recommended for use

- Vardenafil is a further phosphodiesterase type 5 (PDE-5) inhibitor licensed for the treatment of ED.

Points for local consideration:

- Vardenafil has similar efficacy to sildenafil and tadalafil in the treatment of ED.
- The side-effect profile of the three available PDE-5 inhibitors appears similar. Visual disturbances have been reported with sildenafil, back pain and myalgia have been reported with tadalafil.
- Vardenafil should be taken 25 to 60 minutes before anticipated sexual activity, which is similar to sildenafil. Tadalafil has the advantage of being able to be taken 30 minutes to 12 hours before anticipated sexual activity and its duration of action may exceed 24 hours.

- All PDE-5 inhibitors are priced similarly.
- Vardenafil is likely to be subject to the same NHS prescribing restrictions as other drug treatments for ED in terms of Schedule 11 of the National Health Service (General Medical Services) (Scotland) Regulations 1995.

Biphasic insulin aspart (NovoMix® 30) – diabetes mellitus

➤ **Recommended for use**

- Novomix® 30 is a biphasic suspension of insulin aspart. Due to its rapid onset of action (10-20 mins) it is licensed for administration immediately prior to, or when necessary, immediately after a meal.
- Further to a resubmission by the manufacturer, the SMC has revised its original biphasic insulin aspart advice issued in July 2002 (refer to Tayside ADTC Supplement Issue No. 20).

Points for local consideration:

- In short-term trials of 12 weeks duration, biphasic insulin aspart demonstrates similar efficacy on HbA1c levels to standard biphasic human insulin 30 and biphasic insulin lispro Mix25 (Humalog® Mix25).
- Biphasic insulin aspart 30 and biphasic insulin lispro Mix25 are priced similarly and 10-20% higher than standard biphasic human insulin 30 (Human Mixtard® 30) depending on the cartridge/pen device used.
- Biphasic insulin aspart 30 should be reserved for patients having difficulty achieving adequate control with standard biphasic insulin. The majority of prescribing is anticipated to follow a recommendation from the diabetic clinic.

Recently Launched Medicines Awaiting SMC Evaluation

New medicines should not normally be prescribed until a recommendation for use has been issued by the SMC. Refer to D&TC Supplement Issue No. 26 for details of exceptional use prior to a SMC recommendation.

The following are examples of medicines that have been launched but have not, as yet, been considered by the SMC and are, therefore, **not recommended** for prescribing at the current time.

Buprenorphine patches (Transtec®)
 Cilostazol (Pletal®)
 Ezetimibe (Ezetrol®)
 Memantine (Ebixa®) – advice due August

Details of local recommendations for new medicines are available on the Tayside D&TC web-site (www.show.scot.nhs.uk/thb/adtc). Information on which new medicines will be considered by the SMC over the next two to three months is available on the SMC web-site (www.scottishmedicines.org.uk) under “Work Programme”.

Contact details:

Local implementation of SMC recommendations is being taken forward by the Tayside Medicines Unit – contact Jan Jones, Pharmaceutical Prescribing Adviser (jan.jones@tpct.scot.nhs.uk) if you have any queries in relation to the introduction of new drugs within NHS Tayside.

This bulletin is based on evidence available to the Tayside Medicines Unit at time of publication and is covered by the Disclaimer and Terms & Conditions of use and access to the NHS Tayside Drug & Therapeutics Committee web-site (www.show.scot.nhs.uk/thb/adtc).