EMERGENT THERAPIES

Novel hay fever formulation shows improved symptom control

A new nasal spray offering fast and powerful symptomatic control of allergic rhinitis (AR) has been launched in the UK by Meda Pharmaceuticals.

Dymista®, a novel formulation of fluticasone propionate and azelastine hydrochloride, is licensed for the symptomatic treatment of moderate to severe seasonal and perennial AR where monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.

Around one in four people in the UK suffer from perennial or seasonal AR. Of these, over 50% have moderate to severe symptoms, and many remain symptomatic in spite of receiving treatment. A recent UK survey showed that most patients (70.5%) with moderate to severe AR use multiple therapies in an attempt to achieve symptom control, although there is limited evidence to support this practice.[1]

The efficacy and safety of Dymista has been documented in several studies involving over 4000 patients, 1400 of which received the new formulation.

A meta-analysis of three trials involving almost 3400 patients with moderate-to-severe seasonal AR showed that those receiving Dymista achieved significantly better reduction in total nasal symptom score (comprising nasal congestion, runny nose, itchy nose and sneezing) than those given placebo or either fluticasone propionate or azelastine hydrochloride alone.[2]

In a further study, Dymista achieved symptom relief up to 6 days faster than fluticasone propionate monotherapy and 5 days faster than azelastine.[3]

Dymista was well tolerated, the most commonly reported adverse effects being epistaxis, headache and dysgeusia.[2]

According to GP and allergy expert Dr Dermot Ryan, effective management of AR remains a challenge for both healthcare professionals and patients.

"Non-adherence to treatment remains a significant issue, with patients unsure whether current first-line treatments are taking effect, based on their relatively slow onset of action and limited relief of symptoms. The introduction of new treatments such as Dymista that can address these issues is an important development in improving the management of such a common but difficult to manage condition," he said.

REFERENCES
1. Pitman R, Paracha N et al. Episode pattern and healthcare utilisation in patients with seasonal allergic rhinitis. Poster presented at EAACI 2012
2. Carr W et al. *J Allergy Clin Immunol.* 2012;129(5):1282-89
3. Bachert C, Hampel F et al. MP29-02 and time to response in the treatment of seasonal allergic rhinitis compared to marketed antihistamine and corticosteroid nasal sprays. Poster presented at the 30th Congress of the European Academy of Allergy and Clinical Immunology (EAACI) 2011

DYMISTA AT A GLANCE§

Active components
- Azelastine hydrochloride (1mg)
- Fluticasone propionate (365µg)

Indication(s)*
- Moderate to severe seasonal or perennial allergic rhinitis

Dosing frequency
- 1 spray per nostril twice daily

Contraindications†
- None†

Recommended minimum/ maximum age
- Min: 12 years Max: none

Common adverse events (≥1/100)
- Epistaxis; headache, dysgeusia

Link for summary of product characteristics (SmPC)
www.medicines.org.uk/emc/medicine/27579

§ Please note: The information presented for the drugs featured is not comprehensive and is taken from information provided by third party sources. For full information about any drug featured, including special precautions, please see the full summary of product characteristics using the link shown and/or consult the manufacturer.

*See SmPC for full licensed indication
†Hypersensitivity to active components and excipients is a contraindication for all drugs.
‡See SmPC for full details

First pre-prandial GLP-1 receptor agonist may offer savings

A new once-daily parenteral hypoglycaemic is now available in the UK for the management of uncontrolled type 2 diabetes in combination with oral hypoglycaemics and/or insulin.

Lyxumia (lixisenatide) is the first prandial glucagon-like peptide-1 (GLP-1) receptor agonist to be developed, and with a competitive price tag, may represent a cost-effective option for the NHS.

Lixisenatide has been shown to slow down the process of gastric emptying, and thereby lower blood sugar after a meal.

The approval of the new agent is based on a comprehensive trial programme, which included 11 clinical studies and more than 5,000 patients. Results from Phase 3 trials showed that a combination of lixisenatide with basal insulin, plus oral antidiabetic agents such as metformin, significantly reduced levels of HbA1c, compared with placebo, in patients with type 2 diabetes. It also reduced postprandial fasting glucose compared with baseline.

LYXUMIA AT A GLANCE§

Active components
- Lixisenatide (10µg or 20µg) solution

Indication(s)*
- Adults with uncontrolled type 2 diabetes, in combination with oral hypoglycaemic agent

Dosing frequency
- Starting dose: 10µg o.d. for 14 days; maintenance 20µg o.d.

Contraindications†
- None†

Recommended minimum age
- 18 years

Common adverse events (≥1/100)‡
- Hypoglycaemia, headache, gastrointestinal disturbance, infections, dizziness, somnolence, dyspepsia, back pain

Link for summary of product characteristics (SmPC)
www.medicines.org.uk/emc/medicine/27405

New option for long-term contraception

The first subcutaneously delivered formulation of the long-acting reversible contraceptive (LARC) medroxyprogesterone acetate (MPA) has been launched in the UK. Sayana Press is injected into the thigh or abdomen every 13 weeks using a prefilled device (Uniject®).

MPA is a steroidal progestin, a synthetic variant of the human hormone progesterone, which prevents ovulation and provides contraception for 13 weeks (+/- 1 week). In the two phase 3 clinical studies of 1787 women, no pregnancies were reported with subcutaneous MPA.

Over half of the participants in the studies experienced amenorrhea after 12 months, and over half of women did not report any significant weight changes while taking subcutaneous MPA.

In adolescents (12-18 years), use of Sayana Press is only indicated when other contraceptive methods are considered unsuitable or unacceptable.

SAYANA AT A GLANCE§

Active component

medroxyprogesterone acetate (MPA)

Indication(s)*

Long-term reversible female contraception

Dosing frequency

Single injection at 13 week intervals

Main contraindications†

Pregnancy (known or suspected); breast or genital organ malignancy; vaginal bleeding; hepatic impairment; metabolic bone disease; thromboembolic/cerebrovascular disease

Recommended minimum/ maximum age

Min: 12 years. Only rcommended for females aged 12-18 years if other methods are considered unsuitable

Common adverse events (≥1/100)‡

Weight increase; headache; sexual disorders; depression; mood disorder

Link for summary of product characteristics (SmPC)

www.medicines.org.uk/emc/medicine/27798

TECHNOLOGY APPRAISALS

Dapagliflozin (Forxiga)

NICE has published a final appraisal determination (FAD) recommending the use of the novel once-daily oral hypoglycaemic dapagliflozin as a treatment option for adults with type 2 diabetes.

The guidance supports the use of dapagliflozin as dual therapy in combination with metformin, and in combination with insulin with or without other oral antidiabetic drugs. In combination with metformin, dapagliflozin is recommended for use in place of a sulphonylurea (SU) for patients in whom an SU is not tolerated or contraindicated, or those who are at significant risk of hypoglycaemia or its consequences. The addition of dapagliflozin to metformin may also be preferable to a thiazolidinedione if further weight gain is a concern.

Dapagliflozin is the first in a new class of treatments known as SGLT2 inhibitors, which work independently of insulin with a mechanism of action that reduces the amount of glucose reabsorbed in the kidney.

The efficacy and safety of dapagliflozin has been investigated in a comprehensive clinical development programme involving over 5500 patients with type 2 diabetes. Data from these trials show that it effectively lowers HbA1c and maintains glycaemic control in adults with type 2 diabetes for two years. It also has the secondary benefit of weight loss sustained for up to two years and is generally well tolerated.

See 'What are the options after metformin', Page 21

SAFETY RECOMMENDATIONS

European safety agency seeks curbs on pain drugs

Measures to restrict the use of codeine-containing medicines for the management of pain in children were among three recommendations on pain management drugs to emerge from the annual meeting in June this year of the European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC).

The recommendations regarding codeine seek to ensure that such medicines, which have been associated with respiratory depression, are used only in children for whom the benefits are greater than the risks. They include:

Codeine-containing medicines should only be used to treat acute to moderate pain in children above 12 years of age that cannot be relieved by other simple analgesics.

These medicines should not be used at all in patients aged below 18 years who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea, as these patients are more susceptible to respiratory problems.

The PRAC further advised that, as the risk of side effects with codeine may also apply to adults, codeine should not be used in people of any age who are known to be ultra-rapid metabolisers, nor in breastfeeding mothers.

The Committee also published recommendations on two other analgesic agents prescribed commonly in primary care:

- **Diclofenac: the Committee warned that the cardiovascular effects of this NSAID when given systemically are similar to those of selective COX-2 inhibitors. This applies particularly when diclofenac is used at a high dose (150mg daily) and for long-term treatment.**
- **Flupirtine (oral and suppository formulations) should only be used to treat acute (short-term) pain in adults who cannot use other suitable pain agents (such as NSAIDs and weak opioids) and treatment should not exceed 2 weeks because of the risk of damage to the liver.**

The PRAC recommendation will need to go through a number of hoops before adoption of any EU-wide legally binding decisions.

For more details visit: www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/06/event_detail_000602.jsp&mid=WC0b01ac058004d5c3