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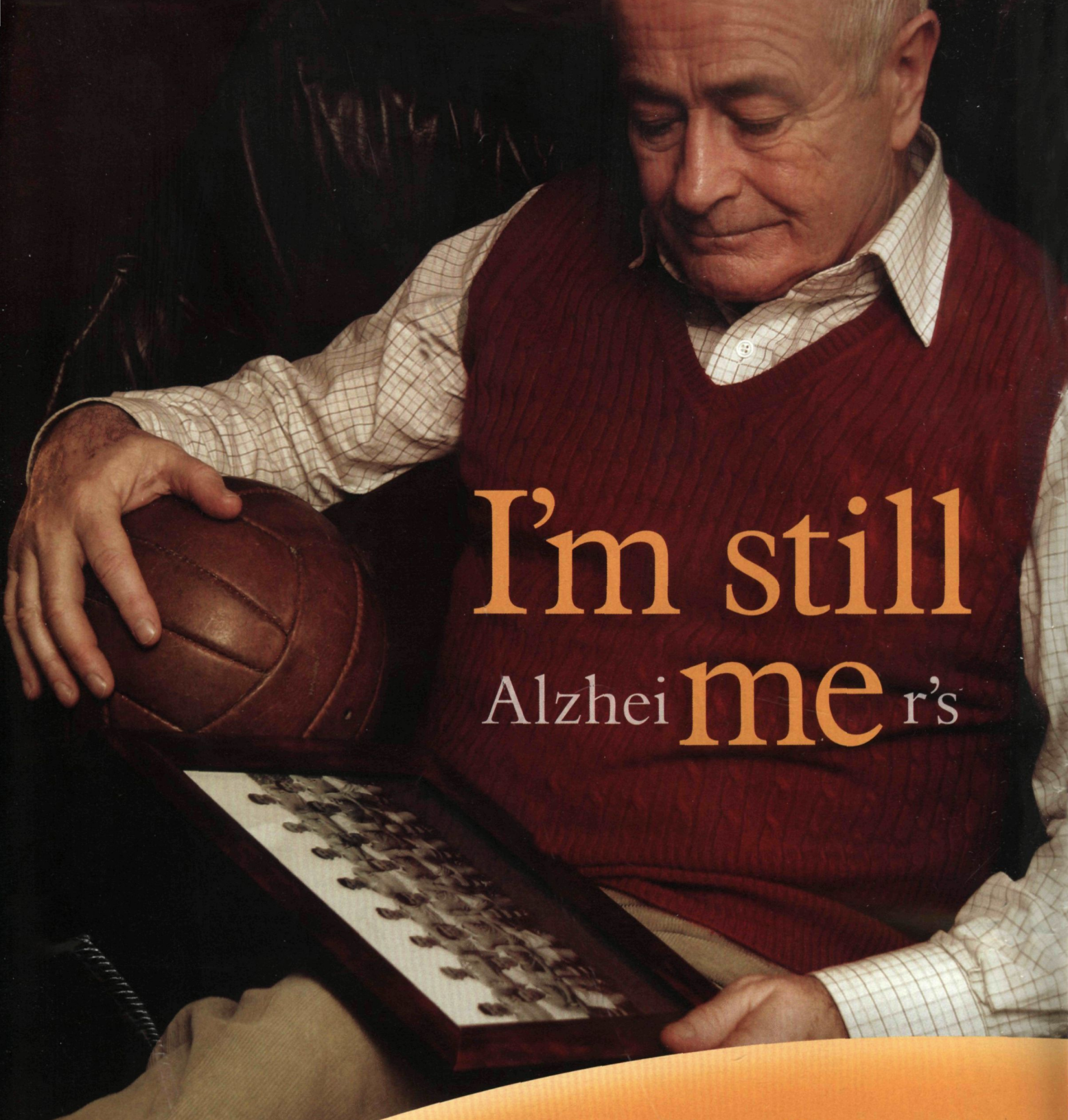

once daily
Aricept
donepezil hydrochloride

Making a difference in Alzheimer's

Abbreviated Prescribing Information for ARICEPT™ (donepezil) - Republic of Ireland
ARICEPT Film-coated Tablets (donepezil hydrochloride)
Please refer to the SmPC before prescribing ARICEPT 5 mg or ARICEPT 10 mg. Indication: Symptomatic treatment of mild to moderately severe Alzheimer's dementia. **Dose and administration:** ***Adults/elderly;*** 5 mg daily which may be increased to 10 mg once daily after at least one month. Initiation and supervision by a physician with experience of Alzheimer's dementia. A caregiver should be available to monitor compliance. Regular monitoring to ensure continued therapeutic benefit, consider discontinuation when evidence of a therapeutic effect ceases. No dose adjustment necessary for patients with renal impairment. Dose escalation, according to tolerability, should be performed in patients with mild to moderate hepatic impairment. ***Children;*** Not recommended. **Contra-Indications:** Hypersensitivity to donepezil, piperidine derivatives or any excipients used in ARICEPT. **Lactation:** Excretion into breast milk unknown. Women on donepezil should not breast feed. **Warnings and Precautions:** Exaggeration of succinylcholine-type muscle relaxation. Avoid concurrent use of anticholinesterases, cholinergic agonists, cholinergic antagonists. Possibility of vagotonic effect on the heart which may be particularly important with "sick sinus syndrome", and supraventricular conduction conditions. There have been reports of syncope and seizures - in such patients the possibility of heart block or long sinusal pauses should be considered. Careful monitoring of patients at risk of ulcer disease including those receiving NSAIDs. Cholinomimetics may cause bladder outflow obstruction. Seizures occur in Alzheimer's disease and cholinomimetics have the potential to cause seizures and they may also have the potential to exacerbate or induce extrapyramidal symptoms. Care in patients suffering asthma and obstructive pulmonary disease. As with all Alzheimer's patients, routine evaluation of ability to drive/operate machinery. No data available for patients with severe hepatic impairment. This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Drug Interactions:** Experience of use with concomitant medications is limited, consider possibility of as yet unknown interactions. Interaction possible with inhibitors or inducers of Cytochrome P450; use such combinations with care. Possible synergistic activity with succinylcholine-type muscle relaxants, beta-blockers, cholinergic or anticholinergic agents. **Side effects:** Most commonly diarrhoea, muscle cramps, fatigue, nausea, vomiting, and insomnia. Very common effects (>1/10): diarrhoea, nausea, headache. Common effects (>1/100, <1/10): common cold, anorexia, hallucinations, agitation, aggressive behaviour, syncope, dizziness, insomnia, vomiting, abdominal disturbance, rash, pruritis, muscle cramps, urinary incontinence, fatigue, pain, accident. Uncommon effects (>1/1000, <1/100): seizure, bradycardia, gastrointestinal haemorrhage, gastric & duodenal ulcers, minor increases in serum creatine kinase. Rare (>1/100,000,<1/10,000): extrapyramidal symptoms, sino-atrial block, atrioventricular block, liver dysfunction including hepatitis. Very rare (< 1/10000) and not known (cannot be estimated from available data). **Presentation:** Blister packed in strips of 14. ARICEPT 5 mg; white, film coated tablets marked 5 and Aricept, packs of 28. ARICEPT 10 mg; yellow, film coated tablets marked 10 and Aricept, packs of 28. **Marketing authorisation numbers:** ARICEPT 5 mg; PA 822/2/1. ARICEPT 10 mg; PA 822/2/2. **Marketing authorisation holder:** Pfizer Healthcare Ireland. 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24. Ireland. **Date of preparation:** April 2007 **ARI/2007/023**

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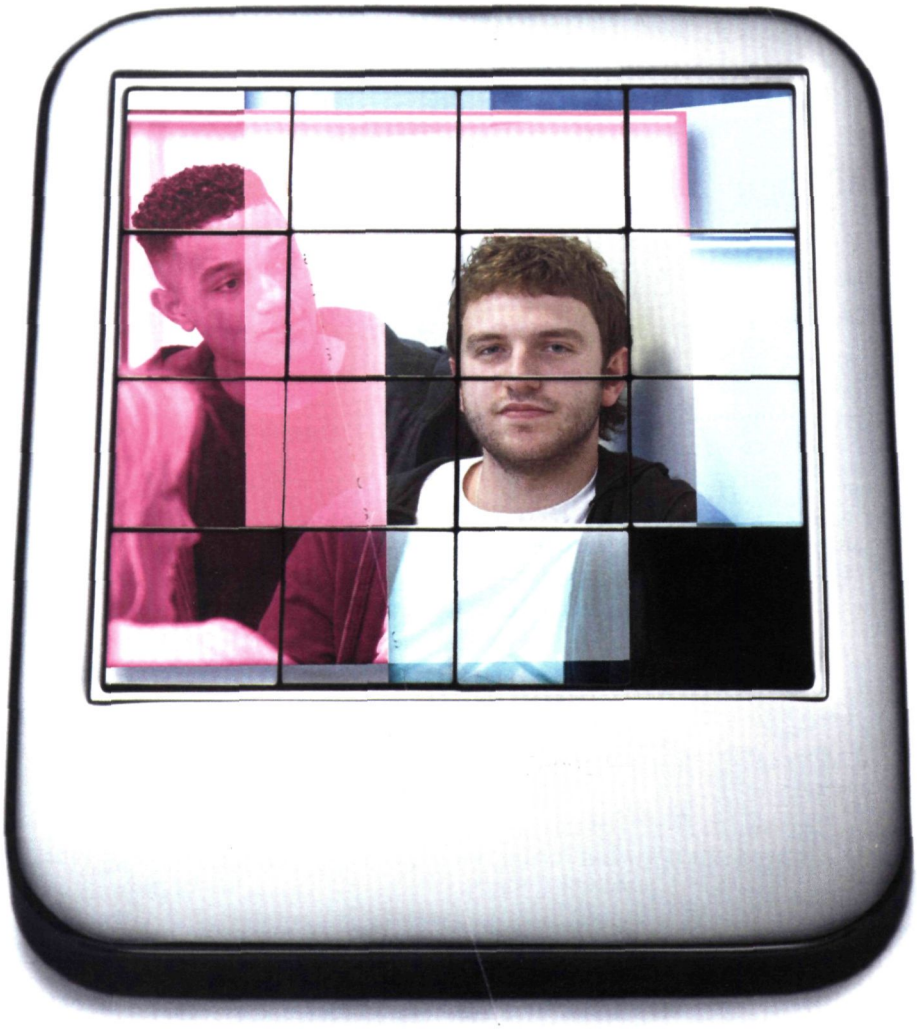
NEW

Once Daily Seroquel XR™
quetiapine



Putting the pieces in place

Reach recommended dose of 600mg by day 2*

- **Simple once-daily dosing**
- **Proven efficacy and broad symptom improvement in schizophrenia**[1]

Seroquel XR™

*Refer to SPC. Elderly patients and patients with hepatic impairment should be started on 50mg/day. The dose can be increased in increments of 50mg/day to an effective dose depending on the clinical response and tolerability.

1. Kahn RS et al. Efficacy and tolerability of once daily extended release quetiapine fumarate in acute schizophrenia: A randomized, double-blind, placebo-controlled study. J Clin Psych 2007; 68: 832–842.

Seroquel XR® Abridged prescribing information

(For full details see summary of product characteristics) **Presentations**: Prolonged-release tablets containing 50mg, 200mg, 300mg and 400mg of quetiapine (as quetiapine fumarate). **Uses**: Treatment of schizophrenia and is effective in preventing relapse in stable schizophrenic patients who have been maintained on Seroquel XR. **Dosage and Administration**: Tablets should be administered once daily, without food (at least one hour before a meal) and should be swallowed whole. ***Adults***: The daily dose at the start of therapy is 300mg on Day 1 and 600mg on Day 2 and up to 800mg after Day 2. The dose should be adjusted within the effective dose range of 400mg to 800mg per day depending on clinical response and tolerability. Recommended daily dose is 600mg daily. For maintenance therapy no dosage adjustment is necessary. ***Elderly***: Rate of dose titration may need to be slower and daily therapeutic dose lower than in younger patients. Patients should be started on 50mg/day and can be increased in increments of 50mg/day to an effective dose. ***Children & Adolescents***: Not evaluated. ***Renal Impairment***: No dose adjustment required. ***Hepatic Impairment***: Use with caution. Patients should be started on 50mg/day and can be increased in increments of 50mg/day to an effective dose. **Contra-indications**: Hypersensitivity to quetiapine fumarate or excipients. Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone. **Precautions and warnings**: Known cardiovascular disease (consider slower titration), cerebrovascular disease, or other conditions predisposing to hypotension. Possible initial orthostatic hypotension during the dose titration period. Caution is recommended in patients with a history of seizures. If signs and symptoms of tardive dyskinesia appear dose reduction or discontinuation should be considered. In the event of neuroleptic malignant syndrome discontinue treatment and appropriate medical treatment given. Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases – monitoring advised. QT prolongation was observed with overdose. As with other antipsychotics, caution should be exercised when quetiapine is prescribed in patients with cardiovascular disease or family history of QT prolongation, and when quetiapine is prescribed with medicines known to increase QTc interval and concomitant neuroleptics, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia. Acute withdrawal symptoms such as nausea, vomiting and insomnia have been described after abrupt cessation of antipsychotic drugs including Seroquel. Gradual withdrawal is advisable. Not approved for the treatment of patients with dementia – related psychosis. Contains lactose, patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Undesirable effects**: The most commonly reported Adverse Drug Reactions with quetiapine are somnolence, dizziness, dry mouth, mild asthenia, constipation, tachycardia, orthostatic hypotension and dyspepsia. As with other antipsychotics, weight gain, syncope, neuroleptic malignant syndrome, leucopenia, neutropenia and peripheral oedema, have been associated with quetiapine. For full list of undesirable effects refer to SPC. **Interactions**: Use with caution with other centrally acting drugs and alcohol. CYP3A4 inhibitors such as ketoconazole are contraindicated. Grapefruit juice, phenytoin, carbamazepine, thioridazine. Observe caution when used concomitantly with drugs known to cause electrolyte imbalance or to increase QTc interval. **Pregnancy & lactation**: Safety and efficacy not established. Effects on ability to drive: Patients should be advised not to drive or operate machinery until individual susceptibility is known. **Pharmaceutical precautions**: No special requirements. **Legal category**: POM. S1A **Marketing Authorisation Numbers**: Seroquel XR 50mg, 200mg, 300mg and 400mg PA 970/18/8-11 **Marketing Authorisation Holder(s)**: AstraZeneca Ltd., Horizon Place, 600 Capability Green, Luton, Bedfordshire, LU1 3LU. **Further information on request from**: AstraZeneca Pharmaceuticals (Ireland) Limited, College Park House, 20 Nassau Street, Dublin 2. Tel. 01 609 7100; Fax. 01 679 6650. Abridged Prescribing Information prepared: February 2008. Date prepared: March 2008

AstraZeneca
NEUROSCIENCE

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