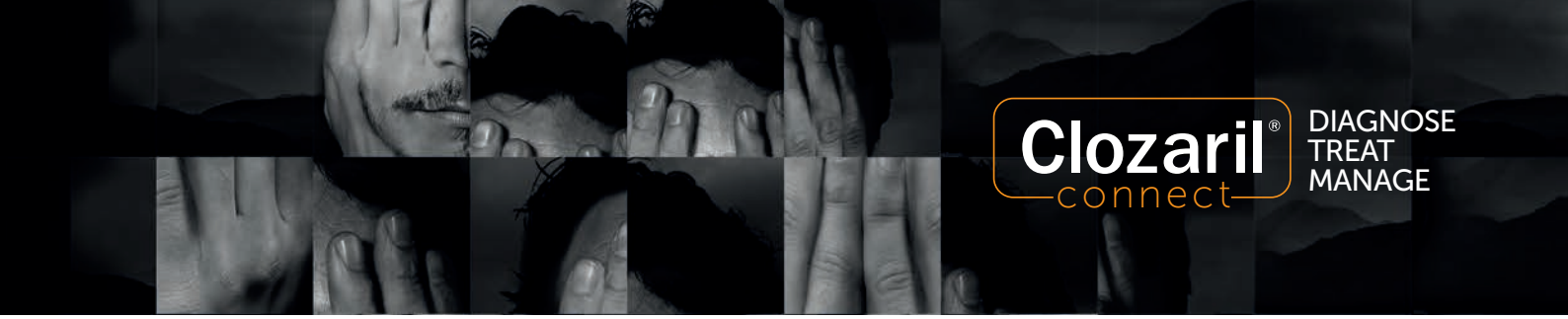


Initiating clozapine treatment

The information in this document is not intended as a definitive treatment strategy, but as a suggested approach for clinicians. It is based on previous successful experience. Each case should, of course, be considered individually.

This information is provided for healthcare professionals and should not be used as a patient information leaflet.

The Summary of Product Characteristics (SmPC) for Clozaril® (clozapine)[1,2] includes the following information regarding initiation of treatment with clozapine:

Treatment-resistant schizophrenic patients

Starting therapy 12.5mg once or twice on the first day, followed by 25mg once or twice on the second day. If well tolerated, the daily dose may then be increased slowly in increments of 25 to 50mg in order to achieve a dose level of up to 300mg/day within 2 to 3 weeks. Thereafter, if required, the daily dose may be further increased in increments of 50 to 100mg at half-weekly or, preferably, weekly intervals.

Switching from a previous antipsychotic therapy to clozapine

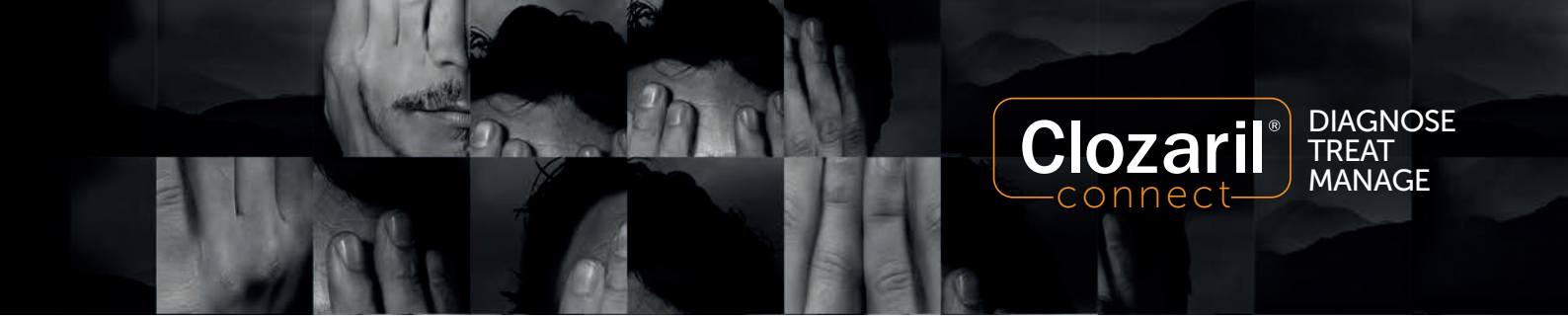
It is generally recommended that clozapine should not be used in combination with other antipsychotics. When clozapine therapy is to be initiated in a patient undergoing oral antipsychotic therapy, it is recommended that the other antipsychotic should first be discontinued by tapering the dosage downwards.

Psychotic disorders occurring during the course of Parkinson's disease, in cases where standard treatment has failed

The starting dose must not exceed 12.5mg/day, taken in the evening. Subsequent dose increases must be by 12.5mg increments, with a maximum of two increments a week up to a maximum of 50mg, a dose that cannot be reached until the end of the second week. The total daily amount should preferably be given as a single dose in the evening.

Patients aged 60 years and older

Initiation of treatment is recommended at a particularly low dose (12.5mg given once on the first day), with subsequent dose increments restricted to 25mg/day.



Before initiating clozapine

Prior to starting clozapine, all patients must be registered with the Clozaril® Patient Monitoring Service (CPMS) and all patients must have a normal pre-treatment white blood cell (WBC) count and absolute neutrophil count (ANC) (WBC >3.5 x 10^9/L, neutrophil count >2.0 x 10^9/L).

Physicians must ensure, to the best of their knowledge, that the patient has never had a WBC blood count <3.0x10^9/L and/or a neutrophil count <1.5x10^9/L and not previously experienced an adverse haematological reaction to clozapine that necessitated its discontinuation.

Patients who have low WBC counts because of benign ethnic neutropenia (BEN) should be given special consideration and should only be started on clozapine with the agreement of a haematologist. These patients can be registered with the CPMS and monitored under modified parameters. For further information, please refer to the Clozapine and benign ethnic neutropenia factsheet.

Before initiating clozapine therapy patients should have a blood test and a history and physical examination. Patients with history of cardiac illness or abnormal cardiac findings on physical examination should be referred to a specialist for other examinations that might include an ECG, and the patient treated only if the expected benefits clearly outweigh the risks. The treating physician should consider performing a pre-treatment ECG.

For full information on listed contraindications and special warnings and precautions, please refer to the SmPC for Clozaril®.[1,2]

References

1. Clozaril (clozapine) Summary of Product Characteristics (online). Mylan Products Ltd. http://www.medicines.org.uk/emc/ (Accessed on 12/04/2018).
2. Clozaril (clozapine) Summary of Product Characteristics (online). BGP Products Ireland Limited. http://www.medicines.ie/ (Accessed on12/04/2018).

Adverse events should be reported.
For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
For Ireland, report adverse events via HPRA Pharmacovigilance medsafety@hpra.ie.
Adverse events should also be reported to Mylan via cpms@mylan.co.uk

Clozaril® (clozapine)

CLOZARIL® Clozapine PATIENT MONITORING SERVICE

NON 2018 0777 Date of preparation: May 2018

Mylan
Better Health for a Better World