

CLOPINE® (clozapine) MONITORING SYSTEM PATIENT PRIVACY STATEMENT

Introduction to the ClopineCentral™ Monitoring System

It is a Therapeutic Goods Administration (TGA) requirement that your healthcare professionals undertake regular monitoring of your white blood cell counts whilst you are taking Clopine. The ClopineCentral™ monitoring system is a web based application that assists your healthcare professionals to monitor certain health indicators, and safeguard against potentially fatal adverse reactions associated with Clopine.

ClopineCentral is facilitated by Pfizer Australia Pty Ltd (**Pfizer** or '**we**'), which is the Australian supplier of Clopine and a part of the Pfizer group of companies (**Pfizer Group**). Pfizer is bound by the Privacy Act 1988 (Cth) (**Privacy Act**) and the Australian Privacy Principles (**APPs**).

This Statement provides important information about how, and why your personal information is handled by Pfizer and the Pfizer Group in any use of ClopineCentral. It also describes the categories of information disclosed to Pfizer by your healthcare professionals, and by Pfizer to your healthcare professionals, the Pfizer Group and service providers.

For clarity, your personal information disclosed to Pfizer or any of your healthcare professionals will be handled generally under your healthcare professional(s) privacy policy and applicable privacy terms. Your healthcare professional(s) can provide such policy and terms.

Personal information processed by ClopineCentral

Collection and Processing of information: Pfizer may be provided with the following personal information about you - whether by your relevant healthcare professionals, or otherwise - for inclusion in ClopineCentral:

Scope of Information	Details
Registration Information	<p>As part of the registration process, we or your healthcare professionals will enter into ClopineCentral:</p> <ul style="list-style-type: none"> • your initials, date of birth, weight (optional), blood group and gender • your name, address and telephone number, where necessary for administrative purposes • the name of your healthcare professionals and their respective places of business (this includes your GP, specialist medical practitioner and/or any other prescriber) • your dose of Clopine • our initial blood test results (white blood cell and neutrophil counts) including date of blood test • your relevant medical history (as applicable) including of any bone marrow disorder, neutropenia, cardiac concerns etc.
Pathology and Other Information	<p>Your ongoing blood tests and pathology results will be entered into ClopineCentral, along with:</p> <ul style="list-style-type: none"> • any changes to your dose of Clopine • if you stop Clopine therapy for any reason • the name of the pharmacy which dispenses Clopine to you • your dose of Clopine • any adverse events potentially associated with your general treatment and your use of Clopine.
Additional information that may be processed	<p>Additional healthcare professional notes and information collected by healthcare professionals to assist in monitoring and facilitating clinical management of additional health issues (which may be unrelated to symptoms being treated by Clopine) including potential cardiac changes, cholesterol levels, blood glucose levels, and other general health related parameters.</p> <p>You may choose to withdraw your consent at any time to the collection, storage, use and disclosure of this additional information. You may do this by informing your relevant healthcare professionals.</p>



If you do not provide Pfizer, or your relevant healthcare professionals, with the personal information set out under 'Registration Information' and 'Pathology and Other Information' above, your healthcare professionals may not be able to commence or continue to provide Clopine to you, or use ClopineCentral to support your treatment.

Use and Disclosure of your Personal Information under ClopineCentral

Pfizer will always handle all personal information in accordance with its Privacy Policy, located at www.pfizer.com.au/privacy. The Pfizer Privacy Policy contains full information about how you may access and/or correct the personal information held about you in ClopineCentral, as well as information on making a complaint about any breach of the Privacy Act and APPs, and how Pfizer will deal with any complaints.

Information provided by Pfizer to Healthcare professionals

Pfizer may provide your healthcare professionals involved with access to personal information about you as processed by ClopineCentral to assist them to manage your treatment with Clopine. These healthcare professionals may include your GP, specialist medical practitioner, other prescriber (as applicable), pharmacist and / or the coordinator at your hospital, clinic or other health facility.

Your healthcare professionals may, from time to time, engage Pfizer's consultant hematologist and/or cardiologists for advice to assist them in the monitoring of your treatment with Clopine and these type of specialists may also be provided with your personal information.

Pfizer Group and third party service providers

Pfizer may use and disclose to any member of Pfizer Group your personal information processed and stored on ClopineCentral for a number of reasons, including:

- to administer, develop and improve ClopineCentral;
- to satisfy its (and the Pfizer Group's) regulatory and reporting requirements; and
- as otherwise permitted to disclose the information under the Privacy Act and APPs.

In addition, Pfizer may also engage members of its Group and/or third party service providers (including IT contractors) to administer, support and host ClopineCentral. Your personal information may be disclosed to such Group members and third party service providers in order for them to perform their relevant services to and on behalf of Pfizer.

Some of these recipients may be located outside of Australia (as outlined in the Pfizer Privacy Policy) in locations that may not offer an equivalent level of protection for personal information to the laws of Australia. Pfizer implements appropriate measures to ensure your personal information remains protected and secure when it is transferred outside of Australia in accordance with the Privacy Act, APPs and applicable data protection and privacy laws.

Clozapine Exclusion Database and patient files

In order for Pfizer to comply with its regulatory obligations, some of your personal information in ClopineCentral will be included in the Clozapine Exclusion Database (CED). The CED is a database of patients who have received Clozapine from Pfizer, or other Australian suppliers of Clozapine (including Mylan Health Pty Limited), who are no longer eligible to receive Clozapine due to adverse blood test results. If your blood tests results indicate you should discontinue treatment with Clopine, certain information (including your initials, date of birth, gender, blood group, name of treating healthcare professional and white cell/neutrophil count) will be added to the CED and will be accessible by other Australian suppliers of Clozapine in order to ensure that you do not recommence treatment with Clozapine.

If you have been treated with another brand of Clozapine prior to commencing or resuming treatment with Clopine, your healthcare professional may request that Pfizer arrange for the transfer of your previous blood test results and relevant medical history (including your initials, date of birth, gender, blood group, name of treating healthcare professional, white cell/neutrophil count and specialist notes) (Patient File) to ClopineCentral. Similarly, your healthcare professional may direct Pfizer to transfer your ClopineCentral Patient File to another supplier of Clozapine if you discontinue treatment with Clopine. In either case certain information may be disclosed by Pfizer to the other supplier of Clozapine to facilitate the transfer.



Use of de-identified information

Pfizer may use, collect, store and disclose de-identified and aggregated information for research, statistical and publication purposes. Any information disclosed will be removed of any personal identifiers and will not identify you or any individual. As such, de-identified and aggregated information is not personal information under the Privacy Act or APPs.

If you experience any adverse event associated with your Clopine treatment, Pfizer is also required to provide de-identified information about the adverse event to the TGA. In addition, Pfizer is required to provide de-identified statutory reports to the TGA regarding the national use of Clozapine.

Patient Consent

- I understand and consent to the collection, use and disclosure of my personal information (including my sensitive health information) for the purposes of my healthcare professionals, Pfizer, and members of the Pfizer Group monitoring and facilitating clinical management for health conditions, including monitoring of blood test results as part of my Clopine treatment, each in the manner set out in this Privacy Statement.
- I also understand that my healthcare professionals and Pfizer will collect, use, disclose and handle my personal information in accordance with their respective Privacy Policies

Patient name (and authorised representative, if applicable)

Patient (or authorised representative) **signature**

Date: _____

Medical Practitioner Acknowledgment

I am the patient's medical practitioner / healthcare professional and I confirm that I have explained to my patient why the collection, storage, use and disclosure of their personal information is required for their treatment with Clopine and have received consent from the patient to collect, use and disclose their personal information (including sensitive health information) to Pfizer, each member of the Pfizer Group and each required recipient as set out in the Privacy Statement for the purposes of: (i) providing the patient with Clopine treatment; and (ii) and monitoring blood test results and monitoring for health conditions that are subject to special warnings and precautions as described in the Clopine Product Information and as otherwise set out in the Privacy Statement.

Medical practitioner name

Medical practitioner signature

Date: _____

