

Novartis Pharmaceuticals Corporation
1301 Avenue of the Americas
New York, NY 10020-1301

Novartis Pharmaceuticals Corporation
1301 Avenue of the Americas
New York, NY 10020-1301

Novartis Pharmaceuticals Corporation
Clozapine (Clozaril)
24 mg tablets
1301 Avenue of the Americas¹

■ 1301

Novartis Pharmaceuticals Corporation
1301 Avenue of the Americas
New York, NY 10020-1301

■ 1301

Novartis Pharmaceuticals Corporation
1301 Avenue of the Americas
New York, NY 10020-1301

Novartis Pharmaceuticals Corporation
1301 Avenue of the Americas
New York, NY 10020-1301

1. DSM-IV criteria for schizophrenia
2. Clozapine tablets 24 mg
4 mg tablets
24 mg tablets
15 mg tablets
400 mg tablets
GAF score 41 or higher
3. Clozapine tablets 18 mg
4. Clozapine tablets 65 mg
5. Visit 1 BPRS score 45 or higher
6. Clozapine tablets 1301

■ 1301

43

■ 1301

2. Clinical Global Impression of Change (CGI-C)

CGI-C is a 7-point scale used to assess the change in a patient's condition since the start of treatment. The scale ranges from 1 (Very much improved) to 7 (Very much worse). The scale is as follows:

1. Very much improved
2. Much improved
3. Minimally improved
4. No change
5. Minimally worse
6. Much worse
7. Very much worse

3. Clinical Global Impression of Severity (CGI-S)

CGI-S is a 7-point scale used to assess the severity of a patient's condition. The scale ranges from 1 (Normal, not at all ill) to 7 (Among the most extremely ill patients). The scale is as follows:

CGI-S is a 7-point scale used to assess the severity of a patient's condition. The scale ranges from 1 (Normal, not at all ill) to 7 (Among the most extremely ill patients). The scale is as follows:

1. Normal, not at all ill
2. Borderline mentally ill
3. Mildly ill
4. Moderately ill
5. Markedly ill
6. Severely ill
7. Among the most extremely ill patients

CGI-S is a 7-point scale used to assess the severity of a patient's condition. The scale ranges from 1 (Normal, not at all ill) to 7 (Among the most extremely ill patients). The scale is as follows:

1. Normal, not at all ill
2. Borderline mentally ill
3. Mildly ill
4. Moderately ill
5. Markedly ill
6. Severely ill
7. Among the most extremely ill patients

CGI-S

- DIEPSS (Drug Induced Extra-Pyramidal Symptoms Scale)
- CGI-S

■ CGI-S

BPRS is a 18-item scale used to assess the severity of a patient's condition. CGI-C and CGI-S are used to assess the change in a patient's condition since the start of treatment. BPRS is a 18-item scale used to assess the severity of a patient's condition. CGI-C and CGI-S are used to assess the change in a patient's condition since the start of treatment. BPRS is a 18-item scale used to assess the severity of a patient's condition. CGI-C and CGI-S are used to assess the change in a patient's condition since the start of treatment.

■ CGI-S

BPRS is a 18-item scale used to assess the severity of a patient's condition. BPRS is a 18-item scale used to assess the severity of a patient's condition. BPRS is a 18-item scale used to assess the severity of a patient's condition.

■ CGI-S

Image

背景因子	カテゴリー	例数 (N=43) n (%)
性別	男 女	23 (53.5) 20 (46.5)
年齢	18歳以上30歳未満 30歳以上40歳未満 40歳以上	4 (9.3) 20 (46.5) 19 (44.2)
	平均値 (標準偏差) 中央値 (最小値～最大値)	39.0 (8.96) 38.0 (22～60)
罹病期間	10年未満 10年以上20年未満 20年以上	6 (14.0) 22 (51.2) 15 (34.9)
	平均値 (標準偏差) 中央値 (最小値～最大値)	17.6 (7.8) 18.0 (3.7～40.0)

Page 10 of 10

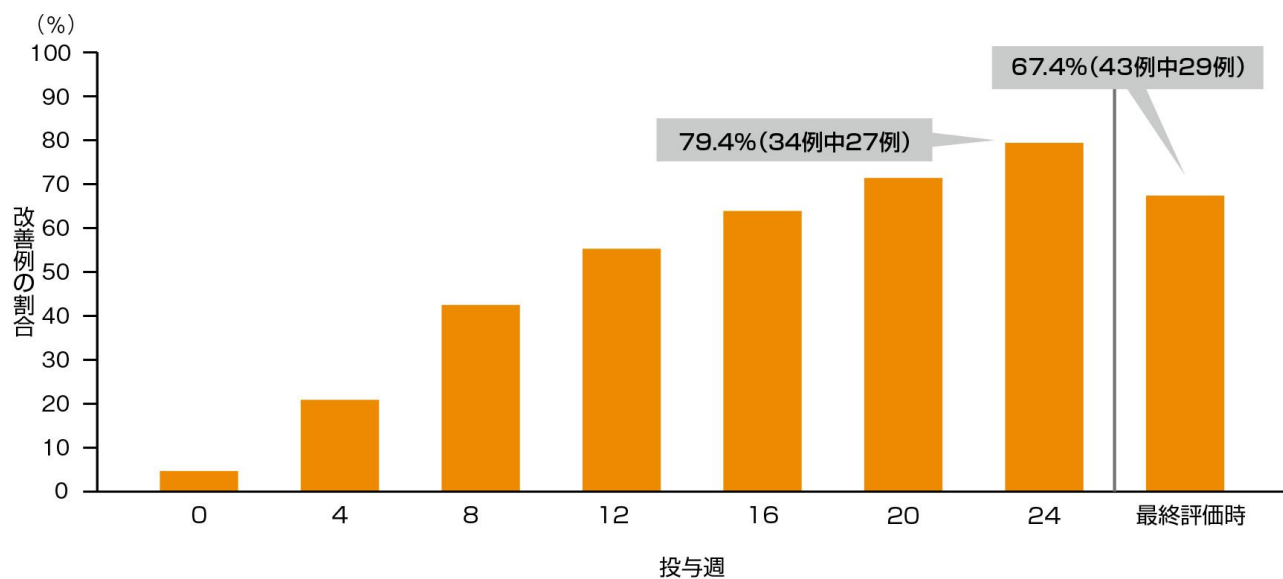
□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □

副作用 (MedDRA PT)	N=43
	n (%)
副作用発現症例数	42 (97.7)
傾眠	32 (74.4)
流涎過多	18 (41.9)
便秘	15 (34.9)
アラニン・アミノトランスフェラーゼ (ALT) 増加	11 (25.6)
悪心	10 (23.3)
嘔吐	9 (20.9)
白血球数増加	9 (20.9)

24週間の治験期で認められた事象

112.3 CPMS-J
CPMS-J

BPRS合計スコア20%以上の改善例の割合



CGI-C

CGI-Cは、投与12週時、投与24週時、最終評価時の3時点において、改善例の割合を評価する。投与12週時の改善例の割合は38例（17例）で44.7%、投与24週時の改善例の割合は38例（3例）で7.9%、最終評価時の改善例の割合は26例（14例）で53.8%であった。

Image

CGI-C評価（看護師）

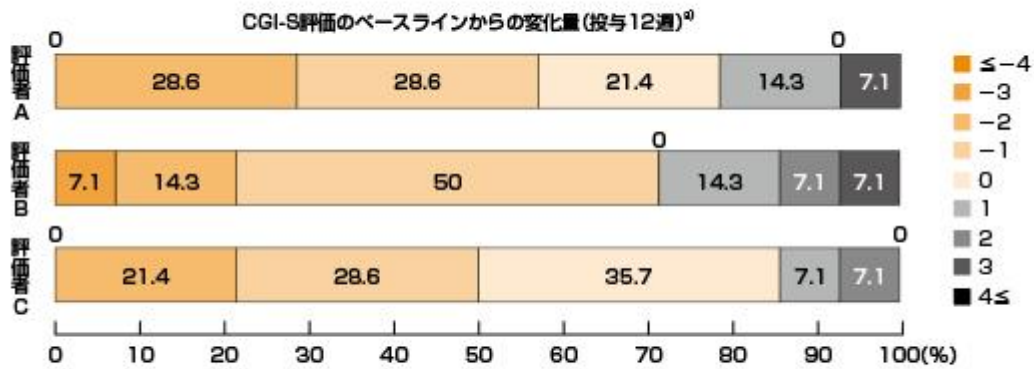


CGI-S

BPRSスコアは、投与12週時、投与24週時、最終評価時の3時点において、CGI-Sスコアを評価する。投与12週時の改善例の割合は14例（8例）で57.1%、投与24週時の改善例の割合は10例（7例）で50.0%、最終評価時の改善例の割合は14例（3例）で21.4%、投与4週時の改善例の割合は28.6%、投与2週時の改善例の割合は14.3%であった。

Image

CGI-S評価(第三者評価者)〈患者14例〉



a) CGI-Sは「1.正常」～「7.非常に重度の精神疾患」の計7段階で評価しており、スコアが高いほど重度の精神症状を示す。登録前をベースラインとする

□□□□

1 Clozapine 24 CLEX123J1301

[illegible]

□□□□□||□□□□1201□□□□

[illegible][illegible]

□ □ □ □ □ □ □ □ □ □ □ □

<mailto:clozaril.remote@novartis.com>

☐☐☐☐ 0800-222-8814☐☐☐☐☐☐☐☐

□□□□ □□□ 9□00□17□30□□□□□□□□□□□□□□

□ □ □ □ □ □ □ □ □ □

0120-003-293

□□□□ □□□ 9□00□17□30□□□□□□□□□□□□□□