



Summary of Investigation Results

Antipsychotic agents, etc.

March 31, 2020

Non-proprietary name

- a. Spiperone
- b. Sultopride hydrochloride
- c. Sulpiride
- d. Timiperone
- e. Nemonapride
- f. Haloperidol
- g. Haloperidol decanoate
- h. Pipamperone hydrochloride
- i. Pimozide
- j. Fluphenazine decanoate
- k. Blonanserin
- l. Bromperidol
- m. Perospirone hydrochloride hydrate
- n. Mosapramine hydrochloride
- o. Aclatonium napadisilate

Branded name (marketing authorization holder)

See Attachment.

Indications

See the attachment.

Summary of revisions

a, d, e, h

With the addition of “dementia with Lewy bodies,” the subject of precaution should be revised to “Patients with Parkinson's disease or dementia with Lewy bodies” in the Contraindications section.

b, f, g, j, l, n, o

With the addition of “dementia with Lewy bodies,” the subject of precaution should be revised to “Patients with Parkinson's disease or dementia with Lewy bodies” in the Contraindications section.

k, m

With the addition of “dementia with Lewy bodies,” the subject of precaution should be revised to “Patients with Parkinson's disease or dementia with Lewy bodies” in the Careful Administration/PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section.

c

With the addition of “dementia with Lewy bodies,” the subject of precaution should be revised to “Patients with Parkinson's disease or dementia with Lewy bodies” in the Careful Administration/PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section.

i

“Patients with depression or Parkinson’s disease” in the Contraindication section as the subject of precaution should be separated into “Patients with depression” and “Patients with Parkinson’s disease or dementia with Lewy bodies” with the addition of “dementia with Lewy bodies” to the latter.

Investigation results and background of the revision

Given that “Parkinson's disease dementia” is a disease condition of Parkinson’s disease and considering the similarity between “Parkinson's disease dementia” and “dementia with Lewy bodies” that has been noted recently, it was considered appropriate to explicitly add “patients with dementia with Lewy bodies” as the subject of precaution in the drugs currently including precautions regarding administration to patients with Parkinson's disease in the Contraindications or Careful Administration/PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS sections. MHLW/PMDA concluded that



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revision of the package insert was necessary based on the results of this investigation and in consultation with expert advisors.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

Cases involving extrapyramidal symptoms

a to o

No cases have been reported to date.

No patient mortalities have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).



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Attachment

	Non-proprietary name	Brand name (Marketing authorization holder)	Indications
a	Spiiperone	Spiropitan Tablets 0.25 mg, 1 mg (Sannova Co., Ltd.)	Schizophrenia
b	Sultopride hydrochloride	Barnetil Tab. 50, 100, 200, Barnetil Fine Granule 50% (Kyowa Pharmaceutical Industry Co., Ltd.), and others	Mania, excitement and hallucination/paranoid state of schizophrenia
c	Sulpiride	Abilit Tablets 50 mg, 100 mg, 200 mg (Sumitomo Dainippon Pharma Co., Ltd.), and others	Abilit Tablets 50 mg : <ul style="list-style-type: none">• Gastric/gastroduodenal ulcer• Schizophrenia• Depression/depression state Abilit Tablets 100 mg, 200 mg: <ul style="list-style-type: none">• Schizophrenia• Depression/depression state
c	Sulpiride	Dogmatyl Tablets 50 mg, 100 mg, 200 mg, Dogmatyl Fine Granules 10%, 50%, Dogmatyl Capsules 50 mg, Dogmatyl Intramuscular Injection 50 mg, 100 mg (Astellas Pharma Inc.)	Dogmatyl Tablets 50 mg, Dogmatyl Capsules 50 mg, Dogmatyl Fine Granules 10%, 50% : <ul style="list-style-type: none">• Gastric/gastroduodenal ulcer• Schizophrenia• Depression/depression state Dogmatyl Tablets 100 mg, 200 mg : <ul style="list-style-type: none">• Schizophrenia• Depression/depression state Dogmatyl Intramuscular Injection 50 mg : <ul style="list-style-type: none">• Gastric/gastroduodenal ulcer



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			al ulcer • Schizophrenia Dogmatyl Intramuscular Injection 100 mg : Schizophrenia
d	Timiperone	Tolopelon Tablets 0.5 mg, 1 mg, 3 mg, Tolopelon Fine Granules 1%, Tolopelon Injection 4 mg (Alfresa Pharma Corporation), and others	Tolopelon Tablets 0.5 mg, 1 mg, 3 mg, Tolopelon Fine Granules 1% : Schizophrenia Tolopelon Injection 4 mg : Schizophrenia, mania
e	Nemonapride	Emilace Tablets 3 mg, 10 mg (LTL Pharma)	Schizophrenia
f	Haloperidol	Serenace Tablets 0.75 mg, 1 mg, 1.5 mg, 3 mg, Serenace Fine Granules 1%, Serenace Oral Solution 0.2%, Serenace Injection 5 mg (Sumitomo Dainippon Pharma Co., Ltd.), and others	Schizophrenia, mania
g	Haloperidol decanoate	Neoperidol injection 50, 100 (Johnson & Johnson K.K.)	Schizophrenia
g	Haloperidol decanoate	Halomonth Injection 50 mg, 100 mg (Janssen Pharmaceutical K.K.)	Schizophrenia
h	Pipamperone hydrochloride	Propitan Tablets 50 mg, Propitan Powder 10% (Sannova Co., Ltd.)	Schizophrenia



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i	Pimozide	Orap Tablets 1 mg, 3 mg, Orap Fine Granules 1% (Astellas Pharma Inc.)	<ul style="list-style-type: none">SchizophreniaThe following symptoms involving autism disorder and mental retardation in pediatric patients Abnormal behaviour in movement, emotional reaction, volition, interpersonal relation, etc. Pathological symptoms observed in sleep, diet, excretion, language, etc. Psychiatric symptoms with stereotypy, etc.
j	Fluphenazine decanoate	Fludecasin Intramuscular Injection 25 mg (Mitsubishi Tanabe Pharma Corporation)	Schizophrenia
k	Blonanserin	Lonasen Tablets 2 mg, 4 mg, 8 mg, Lonasen Powder 2%, Lonasen Tape 20 mg, 30 mg, 40 mg (Sumitomo Dainippon Pharma Co., Ltd.), and others	Schizophrenia
l	Bromperidol	Impromen Tablets 1 mg, 3 mg, 6 mg, Impromen Fine Granules 1% (Janssen Pharmaceutical K.K.), and others	Schizophrenia
m	Perospirone hydrochloride hydrate	Lullan Tablets 4 mg, 8 mg, 16 mg (Sumitomo Dainippon Pharma Co., Ltd.), and others	Schizophrenia
n	Mosapramine hydrochloride	Cremin Tablets 10 mg, 25 mg, 50 mg, Cremin Granules 10% (Mitsubishi Tanabe Pharma Corporation)	Schizophrenia



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o	Aclatonium napadisilate	Abovis Capsule 25, 50 (FUJIFILM Toyama Chemical Co., Ltd.)	Abnormal gastrointestinal functions (nausea, vomiting, inappetence, bloating) in the following conditions: Chronic gastritis, biliary dyskinesia, after gastrointestinal surgery
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