APS Example 1: BLUZJECT Efficacy Handout

Notes about this copydeck:

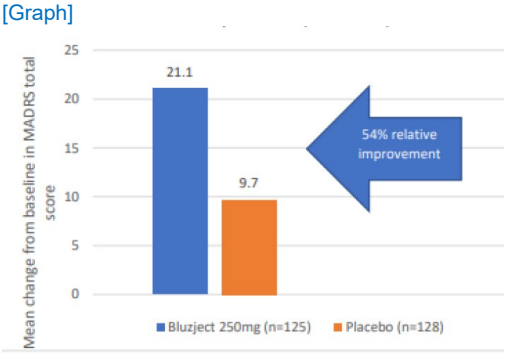
- Submitted as a new APS submission with 0% pickup copy

[PAGE 1 (FRONT)]
[Headline]
BLUZJECT: Demonstrated efficacy in the LEINAD trial[1†]

[Subhead]
Powerful symptom improvement shown in treatment of MDD

[Graph title]
Statistically significant improvement in MADRS total score demonstrated with BLUZJECT 250 mg IM vs. placebo at week 24 (p<0.001)[1] [PM 31D]

[Graph]



[Graph copy]

X-axis label	BLUZJECT 250mg (n=125) Placebo (n=128) [PM 30A]
Y-axis label	Mean change from baseline in MADRS total score
BLUZJECT mean change from baseline	22.1 [PM 31C]
Placebo mean change from baseline	9.7 [PM 31C]

[Graph Callout]
54% relative improvement [Calculation for review: (0.211-0.097)/0.211= 54.03%)]

[Graph qualifier]
Baseline MADRS score in both treatment arms: 28.3 [PM 30A]
[Indication copy]
BLUZJECT (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD). [PM 4A]

[Qualifiers]
† Randomized, placebo-controlled, multicentre 24-week study of BLUZJECT 250 mg injected intramuscularly vs. saline injected intramuscularly every 42 weeks in adult patients with MDD. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient-reported quality of life as measure by Quality of Life, Enjoyment and Satisfaction Questionnaire–Short Form. [PM 30A]
IM: intramuscular; MADRS: Montgomery-Asberg Depression Rating Scale.

[Logos]
BLUZJECT
Cardinal Pharmaceuticals

eFile 111111

Eventually accepted: eFile 111111

This copydeck will be the basis for "direct pick-up" in some examples below

[PAGE 2 (BACK)]
[Subhead]
Improvement of overall function shown in treatment of MDD[1]

[Copy]
Demonstrated improvement in function with BLUZJECT 250 mg IM vs placebo as measured by mean change in total SDS score (absolute change -10.8 vs, -7.8, *p*=0.01); secondary endpoint [PM 32A]

[Subhead]
Improvement of quality of life as measured by patient self-report shown in treatment of MDD[1]

[Copy]
Demonstrated improvement in quality of life with BLUZJECT 250m g IM vs placebo as measured by mean change in Quality of Life, Enjoyment and Satisfaction Questionnaire-Short form (absolute change 20.8 vs. 16.0, *p*=0.03); secondary endpoint [PM 32C]

[Fair Balance]
Clinical use:
BLUZJECT has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use BLUZJECT for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B]

Geriatrics (>65 years of age): Caution should be exercised in treating geriatric patients. The lowest effective dose of 125mg injected intramuscularly every 42 days should always be used as the starting dose in elderly patients. [PM 4C]

Contraindication:
- In patients with concurrent use of monoamine oxidase inhibitors [PM 4D]

Most Serious Warnings and Precautions:
Behavioural and emotional changes including self-harm and suicidal ideation: There are clinical trial and post-marketing reports with SSRIs and other newer anti-depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia/psychomotor restlessness, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. [PM 9A]

Other Relevant Warnings and Precautions:
- discontinuation symptoms [PM 9B]
- QT prolongation [PM 10A]
- abnormal bleeding [PM 10B]
- bone fracture risk [PM 10C]
- serotonin toxicity / neuroleptic malignant syndrome [PM 11A]
- angle closure glaucoma [PM 11B]
- activation of mania / hypomania [PM 11C]
- insomnia [PM 11D]
- sexual dysfunction [PM 12A].

For more information:
Consult the product monograph at www.bluzjectPM.ca for important information relating to adverse reactions, interactions, and dosing which have not been discussed in this piece. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.
[References]
Reference:
1. BLUZJECT Product Monograph. Cardinal Pharmaceuticals Canada Inc. July 8, 2021.

[Logos] BLUZJECT Cardinal Pharmaceuticals PAAB; IMC	[Legalese] BLUZJECT® is a registered trademark. © Cardinal Pharmaceuticals Canada Inc.

eFile 111111

Continuation of example copydeck above that will set the reference copy for future examples below

APS Example 2: BLUZJECT HCP Dosing Card

Notes about this copydeck:

- Submitted as a new APS submission with 0% pickup copy

PAGE 1 (FRONT)]

[Corner nabisco]
The first and only SSRI indicated in major depressive disorder injected intramuscularly every 6 weeks.[2†]
[DOF 1A]

[Headline]
BLUZJECT: Recommended dosing in MDD[1‡]

[Copy]
The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375 mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A]

A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B]

The starting and recommended dose for adults 65 years of age or older is 125 mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A]

[Indication copy]
BLUZJECT (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD). [PM 4A]

[Qualifiers]
† Comparative clinical significance is unknown.
‡ Refer to the Product Monograph for complete dosing information.
IM: Intramuscular; SSRI: Selective serotonin reuptake inhibitor

[Logos]
BLUZJECT
Cardinal Pharmaceuticals

[PAGE 2 (BACK)]
[Headline]
Get to know the BLUZJECT Prefilled Syringe (PFS)[1]

[Subhead]
Prefilled syringe with a retractable needle, a needle guard, and add-on finger flange [PM 18B]

[Image] [Art note: please insert PFS image]

[Copy]
BLUZJECT is available in the following formats:

- **BLUZJECT single-use PFS** with needle guard (**375 mg**)
- **BLUZJECT single-use PFS** with needle guard (**250 mg**)
- **BLUZJECT single-use PFS** with needle guard (**125 mg**) [PM 18A]

[Fair Balance]
Consult the product monograph at www.bluzjectPM.ca for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.

References:
1. BLUZJECT Product Monograph. Cardinal Pharmaceuticals Canada Inc. July 8, 2021.
2. Data on File – BLUZJECT First and only. Cardinal Pharmaceuticals Canada Inc. August 20, 2021.

[Logos] BLUZJECT Cardinal Pharmaceuticals PAAB; IMC	[Legalese] BLUZJECT® is a registered trademark. © Cardinal Pharmaceuticals Canada Inc.

eFile 111222

Eventually accepted as eFile 111222

This copydeck will be the basis for "direct pick-up" in some examples below

APS Example 3: BLUZJECT HCP Leave Behind

Notes about this copydeck:

- Submitted as an APS with little new content (≤2 new pages)
    - As such, this submission could qualify for an ARO review, which can be provided at the price of the immediately preceding urgency level (i.e., ARO-2 for the price of ARO-4, ARO-4 for the price of ARO-7, and so on). Please see the fee schedule for more information.

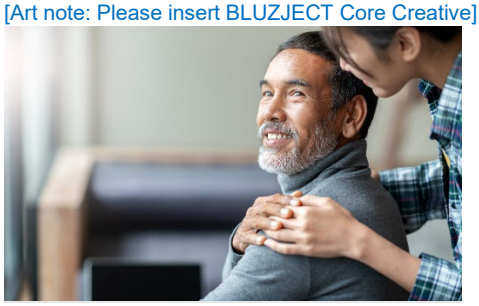
[PAGE 1 (FRONT)]

Previously approved in eFile 111222 HCP Dosing Card
[Corner nabisco]
The first and only SSRI indicated in major depressive disorder injected intramuscularly every 6 weeks.[2†] [DOF 1A]

[Headline]
Confront MDD with BLUZJECT

Previously approved in efile 111222 HCP Dosing Card
[Indication copy]
BLUZJECT (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD).[1] [PM 4A]

[Creative]
[Art note: Please insert BLUZJECT Core Creative]



Previously approved in efile 111222 HCP Dosing Card
[Qualifiers]
† Comparative clinical significance is unknown.

[Logos]
BLUZJECT
Cardinal Pharmaceuticals

eFile 111333

This APS incorporates much of the previously approved efficacy, dosing, and fair balance copy from Example 1 and Example 2. However, it is a new APS and has a new cover page and MOA section (see next page).

Pickup copy is identified via light yellow shading

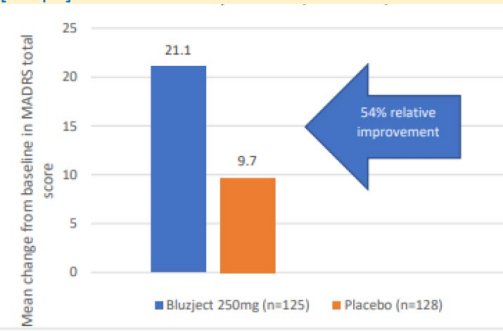
[PAGE 2 (INSIDE LEFT)]

Previously approved in efile 111111 Efficacy Handout
[Headline]
BLUZJECT: Demonstrated efficacy in the LEINAD trial[1†]

[Subhead]
Powerful symptom improvement shown in treatment of MDD

[Graph title]
Statistically significant improvement in MADRS total score demonstrated with BLUZJECT 250 mg IM vs. placebo at week 24 (p<0.001)[1] [PM 31D]

[Graph]



[Graph copy]

X-axis label	BLUZJECT 250mg (n=125) Placebo (n=128) [PM 30A]
Y-axis label	Mean change from baseline in MADRS total score
BLUZJECT mean change from baseline	22.1 [PM 31C]
Placebo mean change from baseline	9.7 [PM 31C]

[Graph Callout]
54% relative improvement [Calculation for review: (0.211-0.097)/0.211= 54.03%)]

[Graph qualifier]
Baseline MADRS score in both treatment arms: 28.3 [PM 30A]

[Qualifiers]
† Randomized, placebo-controlled, multicentre 24-week study of BLUZJECT 250 mg injected intramuscularly vs. saline injected intramuscularly every 42 weeks in adult patients with MDD. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient-reported quality of life as measure by Quality of Life, Enjoyment and Satisfaction Questionnaire–Short Form. [PM 30A]
IM: intramuscular; MADRS: Montgomery-Asberg Depression Rating Scale.

[PAGE 3 (INSIDE RIGHT)]

Previously approved in efile 111222 HCP Dosing Card
[Headline]
BLUZJECT: Recommended dosing in MDD[1†]

[Copy]
The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375 mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A]
A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B]

The starting and recommended dose for adults 65 years of age or older is 125 mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A]

eFile 111333

These examples contain the light yellow shading. The same principles should be applied to the light blue shading for “child files” in series files.

[PM 18A]

[Qualifiers]
† Refer to the Product Monograph for complete dosing information.
IM: Intramuscular; SSRI: Selective serotonin reuptake inhibitor

[PAGE 4 (BACK)]
[Headline]
Mechanism of action of BLUZJECT†

[Copy]
The mechanism of antidepressant effect of bluexetine is thought to be through enhanced serotonin activity through neuromodulation in the CNS. Bluextine binds with low affinity to GABA, norepinephrine and dopamine receptors. The role and contribution of these targets to the overall effect of bluexetine is not fully understood. [PM 20A]

[Qualifier]
† Clinical significance is unknown.

Previously approved in efile 111111 Efficacy Handout
[Fair Balance]
Clinical use:
BLUZJECT has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use BLUZJECT for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B]

Geriatrics (>65 years of age): Caution should be exercised in treating geriatric patients. The lowest effective dose of 125mg injected intramuscularly every 42 days should always be used as the starting dose in elderly patients. [PM 4C]

Contraindication:
- In patients with concurrent use of monoamine oxidase inhibitors [PM 4D]

Most Serious Warnings and Precautions:
Behavioural and emotional changes including self-harm and suicidal ideation: There are clinical trial and post-marketing reports with SSRIs and other newer anti-depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia/psychomotor restlessness, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. [PM 9A]

Other Relevant Warnings and Precautions:
- discontinuation symptoms [PM 9B]
- QT prolongation [PM 10A]
- abnormal bleeding [PM 10B]
- bone fracture risk [PM 10C]
- serotonin toxicity / neuroleptic malignant syndrome [PM 11A]
- angle closure glaucoma [PM 11B]
- activation of mania / hypomania [PM 11C]
- insomnia [PM 11D]
- sexual dysfunction [PM 12A].

For more information:
Consult the product monograph at www.bluzjectPM.ca for important information relating to adverse reactions, interactions, and dosing which have not been discussed in this piece. The product monograph is also available through our medical department by calling 1-800-XXX-XXXX.

[References]
References:

1. BLUZJECT Product Monograph. Cardinal Pharmaceuticals Canada Inc. July 8, 2021.
2. Data on File – BLUZJECT First and only. Cardinal Pharmaceuticals Canada Inc. August 20, 2021.

[Logos] BLUZJECT Cardinal Pharmaceuticals PAAB; IMC	[Legalese] BLUZJECT® is a registered trademark. © Cardinal Pharmaceuticals Canada Inc.

eFile 111333

New MOA copy. No shading applied

Shading should remain throughout the review process (on revisions).

APS Example 4: BLUZJECT HCP Leave Behind 2022 Update

Notes about this copydeck:

- Updates were made to BLUZJECT HCP Leave Behind (Example 3, efile 111333) to reflect the following:
  - A new BLUZJECT injection device to be promoted
  - The manufacturer electing to promote the BLUZJECT HCP site and patient resources instead of the MOA
- Submitted as an APS with little new content (≤2 new pages)
  - As such, this submission could qualify for an ARO review, which can be provided at the price of the immediately preceding urgency level (i.e., ARO-2 for the price of ARO-4, ARO-4 for the price of ARO-7, and so on)
  - Note that this would not be considered as a minor update, nor as a renewal. Please refer to the April 2022 Guidance on Submission Process and Format Requirements for more information on what qualifies as a renewal and as a minor update, and how these submissions can be done using layouts only (no copydecks).

[PAGE 1 (FRONT)]

NOTE TO PAAB: This is an update to BLUZJECT HCP Leave Behind (efile 111333). As such, all content shaded in light yellow is pickup copy from that efile, with specific revisions highlighted in green.

[Corner nabisco]
The first and only SSRI indicated in major depressive disorder injected intramuscularly every 6 weeks.[2†] [DOF 1A]

[Headline]
Confront MDD with BLUZJECT

[Indication copy]
BLUZJECT (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD).[1] [PM 4A]

[Creative]
[Art note: Please insert BLUZJECT Core Creative]

[Qualifiers]
† Comparative clinical significance is unknown.

[Logos]
BLUZJECT
Cardinal Pharmaceuticals

[PAGE 2 (INSIDE LEFT)]
[Headline]
BLUZJECT: Demonstrated efficacy in the LEINAD trial[1†]

[Subhead]
Powerful symptom improvement shown in treatment of MDD

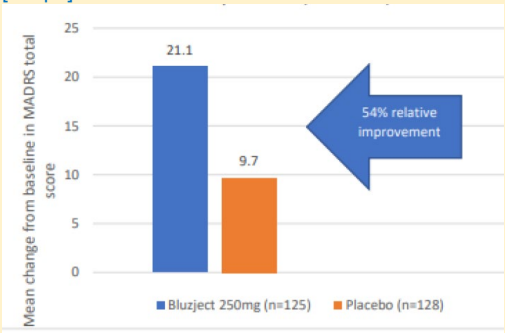
[Graph title]
Statistically significant improvement in MADRS total score demonstrated with BLUZJECT 250 mg IM vs. placebo at week 24 (p<0.001)[1] [PM 31D]

eFile 111444

- Pickup copy is identified via light yellow shading

  Because all the pickup copy originates from the same backfile, a precursory note at the top of the copydeck informs the reviewer about the backfile, rather than citing the same backfile throughout the copydeck

[Graph]



[Graph copy]

X-axis label	BLUZJECT 250mg (n=125) Placebo (n=128) [PM 30A]
Y-axis label	Mean change from baseline in MADRS total score
BLUZJECT mean change from baseline	22.1 [PM 31C]
Placebo mean change from baseline	9.7 [PM 31C]

[Graph Callout]
54% relative improvement [Calculation for review: (0.211-0.097)/0.211= 54.03%)]

[Graph qualifier]
Baseline MADRS score in both treatment arms: 28.3 [PM 30A]

[Qualifiers]
† Randomized, placebo-controlled, multicentre 24-week study of BLUZJECT 250 mg injected intramuscularly vs. saline injected intramuscularly every 42 weeks in adult patients with MDD. The primary endpoint was change in MADRS score from baseline. Key secondary endpoints included change in Sheehan Disability Scale and patient-reported quality of life as measure by Quality of Life, Enjoyment and Satisfaction Questionnaire–Short Form. [PM 30A]
IM: intramuscular; MADRS: Montgomery-Asberg Depression Rating Scale.

[PAGE 3 (INSIDE RIGHT)]

[Headline]
BLUZJECT: Recommended dosing in MDD[1†]

[Copy]
The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375 mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A]

A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B]

The starting and recommended dose for adults 65 years of age or older is 125 mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A]

[Headline]
Get to know the BLUZJECT injection devices[1] (similar to p/a 111222)

[Subhead] Prefilled syringe with a retractable needle, a needle guard, and add-on finger flange [PM 18B]	[Subhead] The BLUZJECT Bluzpen™ with Clickmate™ technology [PM 18B]
[Image] [Art note: please insert PFS image]	[Image] [Art note: please insert Bluzpen image]

eFile 111444

Content that has been revised has been left unshaded.

In this example, the client has highlighted the copy that was changed from a previous file. While this is not required, it is best practice to facilitate an efficient review *(specific colour highlight is not required as long as it is clear and legible)*

[Copy]
BLUZJECT is available in the following formats:

- **BLUZJECT single-use PFS** with needle guard (**375 mg**)
- **BLUZJECT single-use PFS** with needle guard (**250 mg**)
- **BLUZJECT single-use PFS** with needle guard (**125 mg**)
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(375 mg)**
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(250 mg)**
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(125 mg)**

[PM 18A]

[Qualifiers]
† Refer to the Product Monograph for complete dosing information.
IM: Intramuscular; SSRI: Selective serotonin reuptake inhibitor

GE 4 (BACK)]

[Headline]
Visit BluzjectHCP.ca to learn more! [eFile XXXXX0]

[Copy]
Download the following resources to share with your patients prescribed BLUZJECT

- Getting started patient brochure [eFile XXXXX1]
- Dosing calendar [eFile XXXXX2]
- Payment assistance card [eFile XXXXX3]

[Image]
BLUZJECT HCP site thumbnail

[Headline]
~~Mechanism of action of BLUZJECT†~~

[Copy]
~~The mechanism of antidepressant effect of bluexetine is thought to be through enhanced serotonin activity through neuromodulation in the CNS. Bluextine binds with low affinity to GABA, norepinephrine and dopamine receptors. The role and contribution of these targets to the overall effect of bluexetine is not fully understood.~~ ~~[PM 20A]~~

[Qualifier]
~~† Clinical significance is unknown.~~

[Fair Balance]
Clinical use:
BLUZJECT has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use BLUZJECT for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B]

Geriatrics (>65 years of age): Caution should be exercised in treating geriatric patients. The lowest effective dose of 125mg injected intramuscularly every 42 days should always be used as the starting dose in elderly patients. [PM 4C]

Contraindication:

- In patients with concurrent use of monoamine oxidase inhibitors [PM 4D]

Most Serious Warnings and Precautions:
Behavioural and emotional changes including self-harm and suicidal ideation: There are clinical trial and post-marketing reports with SSRIs and other newer anti-depressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia/psychomotor restlessness, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. [PM 9A]

Other Relevant Warnings and Precautions:

- discontinuation symptoms [PM 9B]
- QT prolongation [PM 10A]
- abnormal bleeding [PM 10B]
- bone fracture risk [PM 10C]
- serotonin toxicity / neuroleptic malignant syndrome [PM 11A]
- ….

Content “chunks” that have been revised have been left unshaded, with specific revisions to the previous copy shown with highlights (specific colour highlight is not required as long as it is clear and legible)

If rounds of revisions are happening with different highlight colours selected, a legend at the top of the deck or in the response letter, can be helpful.

Additional examples of way to apply shading:

[PAGE 3 (INSIDE RIGHT)]
[Headline]
BLUZJECT: Recommended dosing in MDD[1†]

[Copy]
The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375 mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A]

A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B]

The starting and recommended dose for adults 65 years of age or older is 125 mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A]

[Headline]
Get to know the BLUZJECT injection devices[1] (similar to p/a 111222)

[Subhead] Prefilled syringe with a retractable needle, a needle guard, and add-on finger flange [PM 18B]	[Subhead] The BLUZJECT Bluzpen™ with Clickmate™ technology [PM 18B]
[Image] [Art note: please insert PFS image]	[Image] [Art note: please insert Bluzpen image]

[Copy]
BLUZJECT is available in the following formats:
- **BLUZJECT single-use PFS** with needle guard (**375 mg**)
- **BLUZJECT single-use PFS** with needle guard (**250 mg**)
- **BLUZJECT single-use PFS** with needle guard (**125 mg**)
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(375 mg)**
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(250 mg)**
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(125 mg)** [PM 18A]

[Qualifiers]
† Refer to the Product Monograph for complete dosing information.
IM: Intramuscular; SSRI: Selective serotonin reuptake inhibitor

[PAGE 4 (BACK)]
[Headline]
Visit BluzjectHCP.ca to learn more! [eFile XXXXX0]

[Copy]
Download the following resources to share with your patients prescribed BLUZJECT
- Getting started patient brochure [eFile XXXXX1]
- Dosing calendar [eFile XXXXX2]
- Payment assistance card [eFile XXXXX3]

[Image]
BLUZJECT HCP site thumbnail

~~[Headline]~~
~~Mechanism of action of BLUZJECT†~~

[Copy]
~~The mechanism of antidepressant effect of bluexetine is thought to be through enhanced serotonin activity through neuromodulation in the CNS. Bluextine binds with low affinity to GABA, norepinephrine and dopamine receptors. The role and contribution of these targets to the overall effect of bluexetine is not fully understood. [PM 20A]~~

~~[Qualifier]~~
~~† Clinical significance is unknown.~~

[Fair Balance]
Clinical use:
BLUZJECT has not been systematically evaluated beyond 24 weeks in controlled clinical trials. The prescriber who elects to use BLUZJECT for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. [PM 4B]

The following partial examples demonstrate other ways which the shading and highlighting can be addressed.

The content has been separated out into cells which are then shaded. Cells which have content that is new, should appear without shading. If it is similar to previously approved copy, the eFile can be quoted and the changes highlighted to facilitate an efficient review. We've coloured the lined red to help visually identify them. This is not a requirement.

[PAGE 1 (FRONT)]

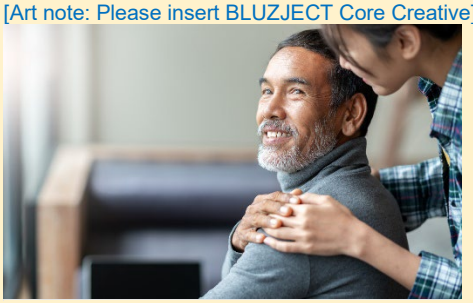
NOTE TO PAAB: This is an update to BLUZJECT HCP Leave Behind (efile 111333). As such, all content shaded in light yellow is pickup copy from that efile, with specific revisions highlighted in blue.

[Corner nabisco]
The first and only SSRI indicated in major depressive disorder injected intramuscularly every 6 weeks.[2†] [DOF 1A]

[Headline]
Confront MDD with BLUZJECT

[Indication copy]
BLUZJECT (bluexetine hydrochloride) is indicated in adults for the symptomatic relief of major depressive disorder (MDD).[1] [PM 4A]

[Creative]
[Art note: Please insert BLUZJECT Core Creative]



p/a 111333

ALT text: women with hand on mans shoulder

[Qualifiers]
† Comparative clinical significance is unknown.

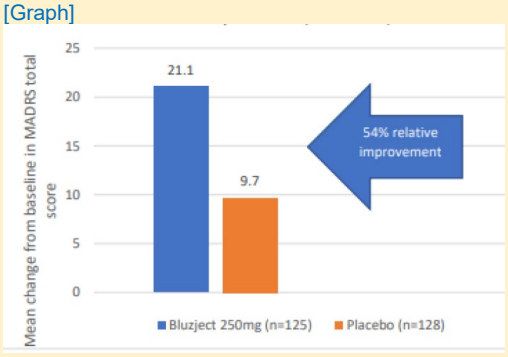
[Logos]
BLUZJECT
Cardinal Pharmaceuticals

[PAGE 2 (INSIDE LEFT)]
[Headline]
BLUZJECT: ~~Demonstrated~~ Superior efficacy in the LEINAD trial[1†]

[Subhead]
Powerful symptom improvement shown in treatment of MDD

[Graph title]
Statistically significant improvement in MADRS total score demonstrated with BLUZJECT 250 mg IM vs. placebo at week 24 (p<0.001)[1] [PM 31D]

[Graph]



[Graph copy]

X-axis label	BLUZJECT 250mg (n=125) Placebo (n=128) [PM 30A]
Y-axis label	Mean change from baseline in MADRS total score
BLUZJECT mean change from baseline	22.1 [PM 31C]
Placebo mean change from baseline	9.7 [PM 31C]

[Graph Callout]
54% relative improvement [Calculation for review: (0.211-0.097)/0.211= 54.03%)]

Here we can see another treatment option for shading. This "cell" format allows for columns where additional information such as references, past eFiles, ALT tags etc. can be included. We've coloured the lined red to help visually identify them. This is not a requirement.

The benefits of this are that it is easy to shade and remove shading for affected sections.

Here, is an example of **incorrect treatment**. It is not acceptable to change one word and still refer to the section as direct pick-up. The change renders the section "new" and shading should be removed. Highlighted copy should never appear over shaded copy. When this happens, the shaded copy is no longer direct pickup.

[PAGE 3 (INSIDE RIGHT)]
[Headline]
BLUZJECT: Recommended dosing in MDD[1†]

[Copy]
The starting and recommended dose for adults less than 65 years of age is 250 mg IM every 6 weeks. Although limited efficacy data is available, some patients not responding to 250 mg may benefit from a higher dose of 375 mg every 6 weeks. The maximum dose should not exceed 375 mg every 6 weeks. It is recommended that responding patients be continued with the lowest dose needed and reassessed periodically to determine the need for continued treatment. [PM 6A]

A dose reduction to 125mg IM every 6 weeks may be considered for patients who do not tolerate higher doses. [PM 6B]

The starting and recommended dose for adults 65 years of age or older is 125 mg IM every 6 weeks. Caution is advised when treating elderly patients. [PM 7A]

p/a 111333

[Headline]
Get to know the BLUZJECT injection devices[1]

[Subhead] Prefilled syringe with a retractable needle, a needle guard, and add-on finger flange [PM 18B]	[Subhead] The BLUZJECT Bluzpen™ with Clickmate™ technology [PM 18B]
[Image] [Art note: please insert PFS image]	[Image] [Art note: please insert Bluzpen image]

[Copy]
BLUZJECT is available in the following formats:
- **BLUZJECT single-use PFS** with needle guard (**375 mg**)
- **BLUZJECT single-use PFS** with needle guard (**250 mg**)
- **BLUZJECT single-use PFS** with needle guard (**125 mg**)
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(375 mg)**
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(250 mg)**
- **BLUZJECT Bluzpen™** with Clickmate™ technology **(125 mg)** [PM 18A]

Similar to p/a 111222

[Qualifiers]
† Refer to the Product Monograph for complete dosing information.
IM: Intramuscular; SSRI: Selective serotonin reuptake inhibitor

p/a 111333

[PAGE 4 (BACK)]
[Headline]
Visit BluzjectHCP.ca to learn more! [eFile XXXXX0]

[Copy]
Download the following resources to share with your patients prescribed BLUZJECT
- Getting started patient brochure [eFile XXXXX1]
- Dosing calendar [eFile XXXXX2]
- Payment assistance card [eFile XXXXX3]

[Image]
BLUZJECT HCP site thumbnail

~~[Headline]~~
~~Mechanism of action of BLUZJECT‡~~

[Copy]
~~The mechanism of antidepressant effect of bluexetine is thought to be through enhanced serotonin activity through neuromodulation in the CNS. Bluextine binds with low affinity to GABA, norepinephrine and dopamine receptors. The role and contribution of these targets to the overall effect of bluexetine is not fully understood.~~ [PM 20A]

[Qualifier]
~~‡ Clinical significance is unknown.~~

[Qualifiers]
† Refer to the Product Monograph for complete dosing information.
IM: Intramuscular; SSRI: Selective serotonin reuptake inhibitor

Here we can see another treatment option for shading.

This addresses PAABs request to identify direct pick-up copy by signalling that everything within the row is direct pick-up.