Claim Package

Canadian ACTOS®/Pioglitazone Settlement

This Claim Package contains:

- A Privacy Statement;
- Instructions for Claimants; and
- A Claim Form

PRIVACY STATEMENT

Personal Information regarding Claimants is collected, used, and retained by the Claims Administrator pursuant to the Personal Information Protection and Electronics Documents Act. S.C. 2000, c.5 (PIPEDA):

- For the purpose of operating and administering the Canadian ACTOS®/Pioglitazone Settlement Agreement ("Settlement");
- To evaluate and consider the Claimant's eligibility under the Settlement; and
- Is strictly private and confidential and will not be disclosed without the express written consent of the Claimant except as provided for in the Settlement.

INSTRUCTIONS FOR CLAIMANTS

If you are completing this Claim Package PRIOR to the Courts' approval of the Settlement, please note that no Claims will be processed unless and until the Settlement has been approved by the Québec and Ontario Courts.

Unless otherwise indicated herein, capitalized terms have the meanings set out in the Settlement.

These instructions provide basic guidelines for submitting claims under the Settlement. In the case of any disagreement between these instructions and the Settlement, the Settlement shall prevail. For more detailed information, please refer to the Settlement Agreement that can be viewed or downloaded at www.piosettlement.ca.

To establish your right to benefits under the terms and conditions of the Settlement, a completed Claim Package must be submitted to the Claims Administrator which shall consist of:

- A completed and signed Claim Form;
- Product Identification Documentation;
- Mandatory Medical Records; and
- All other required documentation as described herein.

All completed Claim Packages must be submitted to the Claims Administrator postmarked **no later than November 29, 2021**, at the following address:

Canadian ACTOS®/Pioglitazone Settlement
Claims Administrator
c/o CA2 Inc.
9 Prince Arthur Avenue
Toronto, ON M5R 1B2

Claimants who have not opted out and who do not submit a completed Claim Package to the Claims Administrator on or before **November 29, 2021**, shall forever forfeit their rights to benefits from the Settlement and will be precluded from ever bringing an action against any of the Released Parties with respect to the Released Claims.

If you require assistance or advice regarding completion of the Claim Package or have any questions related to your claim, you may retain legal counsel at your own expense, or contact the Claims Administrator, free of charge at 1-800-538-0009, or at www.piosettlement.ca. Claimants who retain lawyers or agents in making their claims under the Settlement shall be solely responsible for the fees and expenses of such lawyers or agents.

Claimants may communicate with the Claims Administrator and obtain forms in either English or French. Claimants (or their lawyers/agents) should advise the Claims Administrator of any changes or corrections in address, name, phone number or legal representation.

Please keep copies of all documentation you send to the Claims Administrator. Completing the documentation process takes time. **ACT NOW**. Do not wait until the last few weeks before the Claim Period expires.

Claim Form

Canadian ACTOS®/Pioglitazone Settlement

Strictly Private and Confidential

Section 1: Claimant Identification

I am making a claim as a:

☐ **Class Member**
(the person who used ACTOS® and/or APO-Pioglitazone and/or Sandoz- Pioglitazone)

☐ **Representative of a Class Member**
(a person who is the legal representative of a Class Member who is deceased, a minor and/or otherwise under a legal disability)

Section 2: Class Member Information

Class Member Last Name

First Name

Street Address

P.O. Box

City

Province

Postal Code

Birth Date:
YYYY/MM/DD

Date of Death (if applicable):
YYYY/MM/DD

☐ Official Death certificate attached

Home phone

Work phone

Fax

E-mail

Section 3: Representative Claimant Identification

This section is to be completed ONLY if you are submitting a claim as the Representative of a Class Member. You MUST provide proof of your authority to act as the representative of a Class Member. Before completing this section, you MUST complete Sections 1 and 2 to identify yourself and the Class Member that you are representing.

I am applying on behalf of a Class Member who is:

- ☐ **A minor (under 18 years of age)**
  Please enclose a copy of your authority to act (i.e., long-form birth certificate, baptismal certificate, court order or other proof of guardianship)
- ☐ **A person under legal disability**
  Please enclose a copy of your authority to act (i.e., power of attorney, etc.)
- ☐ **Deceased**
  Please enclose a copy of your authority to act (i.e., will, etc.)

Representative Claimant Last Name

First Name

Street Address

P.O. Box

City

Province

Postal Code

Birth Date:
YYYY/MM/DD

Home phone

Work phone

Fax

E-mail

Section 4: Family Class Member Claims

This section is to be completed ONLY if you are submitting a claim for Family Class Member(s). Family Class Members who are entitled to advance a claim include spouses and children of Class Members for whom a claim is being advanced under the Settlement.

Please include document(s) demonstrating proof of each Family Class Member's relationship to the Class Member and, where the Family Class Member is a minor, under a legal disability or deceased, please include document(s) demonstrating proof of your authority to act (e.g., marriage certificate, long-form birth certificate, baptismal papers, separation agreement, custody judgment, divorce judgment or affidavit, will or other document confirming your authority to act).

Before completing this section, you MUST complete Sections 1 and 2 to identify the Class Member who is your source of entitlement to make a claim. If there is/are more than one Family Class Member making a claim, please copy this section and provide the requested information for each Family Class Member and submit with your Claim Package.

Relationship to Class Member:

Family Class Member Last Name

First Name

Street Address

P.O. Box

City

Province

Postal Code

Birth Date:
YYYY/MM/DD

Home phone

Work phone

Fax

E-mail

Section 5: Legal Representative Identification

This section is to be completed ONLY if a lawyer or agent is representing the Claimant.

Name of Law Firm or Agency

Lawyer or Agent's Last Name

First Name

Street Address

P.O. Box

City

Province

Postal Code

Phone number

Fax

E-mail

Provincial Law Society (if applicable)

NOTE: If you complete Section 5 above, all correspondence will be sent to your legal representative, who must notify the Claims Administrator of any change in mailing address. If you change your legal representation or cease to retain your legal representative, you MUST notify your former legal representative and the Claims Administrator in writing.

Section 6: Products Prescribed

Please indicate whether the Class Member was prescribed any or all of the following:

ACTOS®	☐ **Y**	☐ **N**
Apo-Pioglitazone	☐ **Y**	☐ **N**
Sandoz-Pioglitazone	☐ **Y**	☐ **N**

You must provide Product Identification Documentation sufficient to prove that the Class Member was prescribed and/or provided PIO (i.e., the products ACTOS® and/or APO-Pioglitazone and/or Sandoz-Pioglitazone). You must provide one or more of the following forms of Product Identification Documentation set out below:

a) all pharmacy records reflecting the dispensing of PIO to the Class Member, including the dosage and date(s) of same;

AND/OR

b) all insurance records reflecting the Class Member's purchase of PIO, including the dosage and dates of same, if available;

AND/OR

c) medical records reflecting the prescription and/or provision (samples) of PIO to the Class Member, along with the dosage and dates of same;

OR

d) in extraordinary circumstances only, to be determined by the Claims Administrator, if none of the above records are available, a declaration signed by the Class Member's physician attesting to the Class Member having been prescribed and/or provided with PIO, including the dosage and dates of same, along with a statutory declaration by the Class Member (or the Class Member's representative) that the Class Member was prescribed and/or provided with PIO, along with the dosage and dates of same, and affirming that they have made reasonable best efforts to obtain the above records and providing the reason why such records could not be obtained.

Section 7: Alleged Compensable Injury

Please indicate the Class Member's alleged Compensable Injury which forms the basis of this claim along with date(s) of diagnosis and/or treatment (you may check all that apply but note that compensation is only available once per claim, at the highest confirmed injury level, regardless of the number of potential Compensable Injuries). Please note that this information is intended to assist with the review of your Claim Package. The Claims Administrator will make any and all determinations in respect of the appropriate Compensable Injury following its review of the Class Member's Mandatory Medical Records:

LEVEL 1

☐ Single occurrence of bladder cancer, diagnosed as Ta or Tis, low grade, **OR** a recurrence of bladder cancer originally diagnosed **PRIOR** to the Class Member's PIO usage.

Date (YYYY/MM/DD)

LEVEL 2

☐ Bladder cancer diagnosed as Ta or Tis high grade, **OR** T1, **OR** recurrent bladder cancer, where initial bladder cancer diagnosis was made **AFTER** the Class Member's PIO usage.

Date (YYYY/MM/DD)

LEVEL 3

☐ Bladder cancer diagnosed as T2 **OR** bladder cancer treated with radiation and/or systemic chemotherapy (not including direct bladder instillation treatments).

Date (YYYY/MM/DD)

LEVEL 4

☐ Bladder cancer diagnosed as T3 **OR** bladder cancer resulting in the complete or partial removal of a kidney and/or the bladder.

Date (YYYY/MM/DD)

LEVEL 5

☐ Bladder cancer diagnosed as T4 **OR** death due to bladder cancer.

Date (YYYY/MM/DD)

Section 8: Risk Factors and Other Adjustments

Please indicate which, if any, of the following risk factors apply/ied to the Class Member. Please note that this information is intended to assist with the review of your Claim Package. The Claims Administrator will make any and all determinations of which, if any, of these risk factors exist/ed and will apply the associated adjustments to the base compensation value following its review of the Class Member's Mandatory Medical Records.

1. Was the Class Member diagnosed with bladder cancer prior to first use of PIO?

   ☐ Yes Date of diagnosis (YYYY/MM/DD) _____

   ☐ No

2. Did the Class Member continue using PIO **AFTER** April 19, 2012?

   ☐ Yes

   ☐ No

3. Did/does the Class Member have a history of smoking?

   ☐ Yes

   - ☐ Within one year prior to the date of the Class Member's bladder cancer diagnosis; **OR**
   - ☐ Between one and five years prior to the Class Member's bladder cancer diagnosis; **OR**
   - ☐ More than five but less than twenty years prior to the Class Member's bladder cancer diagnosis.

   ☐ No

4. Did the Class Member have symptoms of bladder cancer (blood in the urine or pain with urination) **PRIOR** to first use of PIO?

   ☐ Yes Date of diagnosis (YYYY/MM/DD) _____

   ☐ No

5. Was the Class Member's bladder cancer diagnosis made more than five (5) years **AFTER** their last use of PIO?

   ☐ Yes

   ☐ No

6. Do the Class Member's Mandatory Medical Records refer to their bladder cancer diagnosis being **causally related** to a history of being exposed to any of the following (check all that apply):

- ☐ Yes
  - ☐ coal gasification
  - ☐ diesel engine exhaust
  - ☐ iron or steel foundries
  - ☐ coke (coal coke or pet coke)
  - ☐ coal tar
  - ☐ carbon black or shale oil extraction
  - ☐ wood impregnation
  - ☐ roofing
  - ☐ road paving
  - ☐ chimney sweeping
  - ☐ aluminum
  - ☐ carbon electrodes
  - ☐ production of rubber, leather, textiles, dyes or paint products
  - ☐ work as a painter, hairdresser, machinist, printer or truck driver
- ☐ No

7. Did the Class Member's bladder cancer originate in another organ and subsequently metastasize or spread to the bladder?

- ☐ Yes
- ☐ No

8. Did the Class Member ever use any pharmaceutical product containing the active compound cyclophosphamide, including the branded medication known as "Cytoxan" and/or "Procytox"?

- ☐ Yes
- ☐ No

9. Did the Class Member ever receive radiation therapy to the pelvis prior to their bladder cancer diagnosis, including for, but not limited to, the treatment of prostate, uterine, cervical, rectal or anal cancer?

- ☐ Yes
- ☐ No

Section 9: Mandatory Medical Records

Please ATTACH and SUBMIT all Mandatory Medical Records with your Claim Package.

Mandatory Medical Records include the documentation described below which you are required to submit in order to be eligible for benefits for a Compensable Injury.

☐ Medical Records reflecting the Class Member's bladder cancer diagnosis, and which must include:

- ☐ Pathology report(s) describing the existence of cancerous cells in the urothelial lining of the urinary bladder, renal pelvis or the ureter or confirming the diagnosis of bladder cancer on biopsy of excised tumor;

OR

- ☐ If no pathology report is available, other contemporaneous medical records referencing a pathology report containing a diagnosis of bladder cancer.

AND

☐ Complete medical records from all healthcare providers who diagnosed and/or provided the Class Members with treatment for their bladder cancer.

AND

☐ If not included in the above, complete medical records from all healthcare providers who prescribed PIO to the Class Member from the date of such first prescription through to the Class Member's last use of PIO.

AND

☐ If not included in the above, complete medical records from the Class Member's primary health care provider for the period spanning three (3) years prior to the Class Member's bladder cancer diagnosis through to the date of the Class Member's bladder cancer diagnosis.

AND

☐ If the death of the Class Member is alleged to be due to bladder cancer, a death certificate, autopsy report or other medical record reflecting that the primary or secondary cause of the Class Member's death was bladder cancer or complications due to the Class Member's bladder cancer.

Section 10: Income Loss Claim

This section **ONLY** applies if you are submitting a claim for a Class Member's alleged income loss.

Income losses will be calculated by the Claims Administrator based on the difference between a Class Member's average net income over the three (3) years prior to the Class Member's Compensable Injury and the Class Member's net income following the Class Member's Compensable Injury.

Date of alleged Compensable Injury (YYYY/MM/DD):

Class Member's Net Income in the **three** years **prior** to the alleged Compensable Injury:

Year		Net income: $	
Year		Net income: $	
Year		Net income: $	
		Average: $	

Class Member's Net Income in the year(s) **following** the alleged Compensable Injury:

Year		Net income: $	
Year		Net income: $	
Year		Net income: $	
Year		Net income: $	
Year		Net income: $	

In order to advance an Income Loss Claim, please submit documentation which reflects the Class Member's net income set out above. All such records will only be reviewed by the Claims Administrator if your claim has been deemed an Approved Claim. All income loss claims are subject to potential adjustments in accordance with Section 12 of the Settlement Agreement.

Section 11: Claimant Declaration

The undersigned hereby consent(s) to the disclosure of the information contained herein to the extent necessary to process this claim for benefits. The undersigned acknowledges and understands that this Claim Form is an official Court document sanctioned by the Ontario and Québec Courts that preside over the Settlement, and submitting this Claim Form to the Claims Administrator is equivalent to filing it with a Court.

After reviewing the information that has been supplied on this Claim Form, the undersigned declares under penalty of perjury that the information provided in this Claim Form is true and correct to the best of his/her knowledge, information and belief.

Signature of Claimant

Print Name

Date (YYYY/MM/DD)

Section 12: Physician Declaration

This Section is to be completed ONLY if you were UNABLE to obtain and provide the Product Identification Documentation required by Section 6 above.

I solemnly declare that:

1. I am a physician licensed to practice medicine in the province of _____.

2. I am/was a treating physician for _____ (Class Member) and I hereby solemnly affirm that the Class Member was prescribed and/or provided with PIO as follows:

ACTOS® ☐ Yes ☐ No

Date(s), duration, and dosage(s)

Apo-Pioglitazone ☐ Yes ☐ No

Date(s), duration, and dosage(s)

Sandoz-Pioglitazone ☐ Yes ☐ No

Date(s), duration, and dosage(s)

Signature of Physician

Date

Name of Physician

Address

Telephone number

Section 13: Claimant Declaration – Missing Product Identification Documentation

This Section is to be completed ONLY if you were unable to obtain and provide the Product Identification Documentation required by Section 6 above.

The undersigned hereby declares under penalty of perjury that the Class Member was prescribed and/or provided with PIO as follows:

ACTOS® ☐ Yes ☐ No

Date(s), duration, and dosage(s)

Apo-Pioglitazone ☐ Yes ☐ No

Date(s), duration, and dosage(s)

Sandoz-Pioglitazone ☐ Yes ☐ No

Date(s), duration, and dosage(s)

The undersigned affirms that reasonable best efforts were made to obtain the required Product Identification Documentation and the following are the reasons WHY such Product Identification Documentation could not be obtained and provided (please attach additional sheets if needed):

Signature of Claimant

Date